CHAPTER 7

SURVEY AND ENFORCEMENT PROCESS FOR SNF's AND NF's

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7000. INTRODUCTION

Sections 7000(ff) implement the nursing home survey, certification, and enforcement regulations at 42 CFR Part 488. No provisions contained in this chapter are intended to create any rights or remedies not otherwise provided in law or regulation.

The nursing home reform regulation establishes several expectations. The first is that providers remain in substantial compliance with Medicare/Medicaid program requirements as well as State law. The regulation emphasizes the need for continued, rather than cyclical compliance. The following enforcement processes allow us to distinguish between those facilities that have quality assurance programs which actively and effectively lead to enhanced quality of care and quality of life for residents, and those facilities that do not. The enforcement processes mandate that policies and procedures be established to remedy deficient practices and to ensure that correction is lasting; specifically, that facilities take the initiative and responsibility for monitoring their own performance continuously to sustain compliance. Measures such as the requirements for a plan of correction emphasize the ability to achieve and maintain compliance leading to improved quality of care. In order for a plan of correction to be acceptable, it must :

1. Contain elements detailing how the facility will correct the deficiency as it relates to the individual;

2. Indicate how the facility will act to protect residents in similar situations;

3. Include the measures the facility will take or the systems it will alter to ensure that the problem does not recur;

4. Indicate how it plans to monitor its performance to make sure that solutions are sustained; and

5. Provide dates when corrective action will be completed.

If a submitted plan of correction does not adequately address all of these points, it would not be acceptable. In addition, the corrective action completion dates must be acceptable to the State. The plan of correction will serve as the facility's allegation of compliance. If an acceptable plan is not submitted, the State Survey agency may propose to the regional office and/or State Medicaid agency that remedies be imposed immediately within applicable notice requirements.

The second expectation is that all deficiencies will be addressed promptly. The standard for program participation mandated by the regulation is substantial compliance. The State and the regional office will take steps to bring about compliance quickly. While HCFA has always had the authority to take prompt enforcement action and impose remedies quickly when appropriate, enforcement timeframes are no longer classified as either 23-day or 90-day tracks. Under the system contained in these sections, action can be taken much sooner. The enforcement team will have the ability to put remedies into place quickly when a situation merits immediate attention. In accordance with §7304, remedies such as civil money penalties, temporary managers, directed plans of correction, in-service training, denial of payment for new admissions, and State monitoring can be imposed before a provider has an opportunity to correct deficiencies.

The third expectation is that residents will receive the care and services they need to meet their highest practicable level of functioning. The process detailed in these sections provides incentives for the continued compliance needed to enable residents to reach these goals.

It should be noted that references to the State will be applicable, as appropriate, to the regional office throughout this chapter when the regional office is the surveying entity. It should also be noted that in cases where the State is authorized by HCFA and/or the State Medicaid agency, the State may impose certain remedies on their behalf, within applicable notice requirements.

7001. DEFINITIONS AND ACRONYMS

Abbreviated Standard Survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change in ownership, management, or director of nursing; or other indicators of specific concern.

Abuse means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, or mental anguish.

Act means the Social Security Act.

Certification of Compliance means that the facility is in at least substantial compliance and is eligible to participate in Medicaid as a nursing facility, or in Medicare as a skilled nursing facility, or in both programs as a dually participating facility.

Certification of Noncompliance means that the facility is not in substantial compliance and is not eligible to participate in Medicaid as a nursing facility, or in Medicare as a skilled nursing facility, or in Medicare and Medicaid as a dually participating facility.

CFR means the Code of Federal Regulations.

Deficiency means a skilled nursing facility or nursing facility=s failure to meet a participation requirement specified in the Act or in 42 CFR Part 483 Subpart B.

Dually Participating Facility means a facility that has a provider agreement in both the Medicare and Medicaid programs.

Educational programs means programs that include any subject pertaining to the long term care participation requirements, the survey process, or the enforcement process.

Enforcement action means the process of imposing one or more of the following remedies: termination of a provider agreement; denial of participation; denial of payment for new admissions; denial of payment for all residents; a temporary manager; civil money penalties; State monitoring; directed plans of correction; directed in-service training; transfer of residents; closure of the facility and transfer of residents; or other HCFA-approved alternative State remedies.

Expanded survey means an increase beyond the core tasks of a standard survey. A standard survey may be expanded at the surveying entity's discretion. When surveyors suspect substandard quality of care they should expand the survey to determine if substandard quality of care does exist.

Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey.

Facility means a skilled nursing facility or nursing facility, or a distinct part of a skilled nursing facility or nursing facility, in accordance with 42 CFR 483.5

HCFA means the Health Care Financing Administration.

Immediate family means a husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

Neglect means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

New admission means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment.

Noncompliance means any deficiency that causes a facility not to be in substantial compliance.

No Opportunity to Correct means the facility will have remedies imposed immediately after a determination of noncompliance has been made.

Nurse aide means any individual providing nursing or nursing-related services to residents in accordance with 42 CFR 483.75(e)(1).

Nursing facility means a Medicaid nursing facility.

OBRA 1987 means the Omnibus Budget Reconciliation Act of 1987.

Opportunity to Correct means the facility is allowed an opportunity to correct identified deficiencies before remedies are imposed.

Partial extended survey means a survey that evaluates additional participation requirements and verifies the existence of substandard quality of care during an abbreviated standard survey.

Per instance civil money penalty means a civil money penalty imposed for each instance of facility noncompliance.

Representative, for purposes of educational programs, means family members, legal guardians, friends, and ombudsmen assigned to the facility.

Skilled nursing facility means a Medicare nursing facility that has a Medicare provider agreement.

Standard survey means a periodic, resident-centered inspection that gathers information about the quality of service furnished in a facility to determine compliance with the requirements of participation.

State survey agency (SA) means the entity responsible for conducting most surveys to certify compliance with Health Care Financing Administration participation requirements.

State Medicaid agency (SMA) means the entity in the State responsible for administering the Medicaid program.

Substandard quality of care means one or more deficiencies related to participation requirements under 42 CFR 483.13, resident behavior and facility practices, 42 CFR 483.15, quality of life, or 42 CFR 483.25, quality of care that constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm. Substantial compliance constitutes compliance with participation requirements.

7002. CHANGE IN CERTIFICATION STATUS FOR MEDICAID NURSING FACILITIES

When Medicaid nursing facility providers wish to participate as Medicare skilled nursing facility providers, the State does not conduct a new survey. The State submits the information obtained during the most recent Medicaid survey and other documentation required for an initial certification of a skilled nursing facility to the regional office.

7004. SKILLED NURSING FACILITY - CITATIONS AND DESCRIPTION

A. Citations.--A skilled nursing facility is defined in §1819(a) of the Act and 42 CFR Part 488.301.

B. Description of Skilled Nursing Facility.--A skilled nursing facility is a facility which:

- Is primarily engaged in providing to residents skilled nursing care and related services for residents who require medical or nursing care; or

- Is primarily engaged in providing to residents skilled rehabilitation services for the rehabilitation of injured, disabled, or sick persons and is not primarily for the care and treatment of mental diseases;

- Has in effect a transfer agreement (meeting the requirements of §1861 (1) of the Act with one or more hospitals having agreements in effect under §1866 of the Act); and

- Meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of §1819 of the Act.

A skilled nursing facility provides a level of care distinguishable both from the level of intensive care furnished by a general hospital and from the level of custodial or supportive care furnished by nursing homes primarily designed to provide daily services above room and board. This level of care is reflected in the participation requirements for skilled nursing facilities. While the requirements call for a wide range of specialized medical services and the employment by the facility of a variety of paramedical and skilled nursing personnel, the emphasis on restorative services is oriented toward providing services for residents who require and can benefit from skilled nursing and one or more types of skilled restorative services, e.g., physical or speech therapy.

7006. NURSING FACILITY - CITATIONS AND DESCRIPTION

A. Citations.--A nursing facility is defined in §1919(a) of the Act and 42 CFR 488.301.

B. Description of Nursing Facility.--A nursing facility is a facility that:

o Is primarily engaged in providing residents with skilled nursing care and related services for residents who require medical or nursing care, rehabilitation services for the rehabilitation of injured, disabled, or sick persons, or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which is available to them only through these facilities, **and is not primarily for the care and treatment of mental diseases;**

o Has in effect a transfer agreement (meeting the requirements of §1861(l) of the Act) with one or more hospitals having agreements in effect under §1866 of the Act; and

o Meets the above requirements and subsections (b) (c), and (d) of §1919 of the Act.

7008. TYPES OF FACILITIES THAT MAY QUALIFY AS SKILLED NURSING FACILITIES AND NURSING FACILITIES

A. A Skilled Nursing Facility or Nursing Facility may be:

o An entire facility for skilled nursing facility or nursing facility care;

o A distinct part of a rehabilitation center;

o A distinct part of a hospital, such as a wing or a section;

o A distinct part of a skilled nursing facility or nursing facility; or

o A religioius non-medical health care institution operated or listed and certified by the First Church of Christ, Scientist, Boston, Massachusetts.

An institution that is primarily for the care and treatment of mental diseases cannot be a skilled nursing facility or nursing facility.

7010. SKILLED NURSING FACILITIES PROVIDING OUTPATIENT PHYSICAL THERAPY, SPEECH PATHOLOGY, OR OCCUPATIONAL SERVICES

A skilled nursing facility may provide Part B outpatient physical therapy, speech therapy, or occupational therapy services either directly or under arrangement.

7012. RESERVED

7014. SPECIAL WAIVERS APPLICABLE TO SKILLED NURSING FACILITIES AND NURSING FACILITIES

A. Waiver of Nurse Staffing Requirements.--

1. Waiver of Seven-Day Registered Nurse (RN) Requirement for Skilled Nursing Facilities.--The requirements for long term care facilities require that a skilled nursing facility provide 24-hour licensed nursing services, an RN for 8 consecutive hours a day, 7 days a week (more than 40 hours a week), and that there be an RN designated as Director of Nursing on a full time basis. The regional office, acting on behalf of the Secretary, may waive the requirement in the following circumstances:

o The facility is located in a rural area and the supply of skilled nursing facility services is not sufficient to meet area needs;

o The facility has one full-time registered nurse regularly on duty 40 hours a week. This may be the same individual or part-time individuals. This nurse may or may not be the Director of Nursing and may perform some Director of Nursing and some clinical duties if the facility so desires; and either;

o The facility has residents whose physicians have indicated, through admission notes or physicians' orders, that the residents do not need RN or physician care for a 48 hour period; or

o A physician or RN will spend the necessary time at the facility to provide care residents need during the days that an RN is not on duty. This requirement refers to clinical care of the residents who need skilled nursing services.

If a waiver is granted, the regional office, acting on behalf of the Secretary, must provide notice of the waiver to the State long term care ombudsman and to the State protection and advocacy system for the mentally ill and mentally retarded. The facility granted such a waiver must notify residents of the facility (or responsible guardians) and members of their immediate families of the waiver.

A waiver of the RN requirement is subject to annual renewal by the Secretary.

2. Waivers of Nurse Staffing Requirements in Nursing Facilities.--The requirements for long term care facilities also require that nursing facilities provide 24-hour licensed nursing, provide an RN for 8 consecutive hours a day, 7 days a week, and that there be an RN designated as Director of Nursing on a full-time basis. The State may waive these requirements if the following conditions are met:

o The facility demonstrates to the satisfaction of the State that it has made diligent efforts to recruit the appropriate personnel and is unable to do so;

o The State determines that a waiver will not endanger the health or safety of the residents in the facility; and

o The State finds that an RN or physician is obligated to respond immediately to phone calls from the facility for periods when licensed nursing services are not available.

The State may grant a waiver from the 24-hour licensed nursing requirement; the 8 consecutive hours a day, 7 days a week requirement, or both. A facility may be waived from the requirement to designate a Director of Nursing if it has been waived from either the requirement to provide 24-hour licensed nursing services or the 8 consecutive hours a day, 7 days a week requirement.

If a waiver is granted, the State must provide notice of the waiver to the State long term care ombudsman and to the State protection and advocacy system for the mentally ill and mentally retarded. The facility granted the waiver must notify residents of the facility (or responsible guardians) and members of their immediate families of the waiver.

3. Waivers of Nurse Staffing Requirements for Skilled Nursing Facilities/Nursing Facilities.--If a facility is dually-participating in both the Medicare and Medicaid programs, it is subject to the waiver criteria for skilled nursing facilities. Therefore, a skilled nursing facility/nursing facility may only have the 8 consecutive hours a day, 7 days a week requirement waived. In this case, the waiver is granted by the regional office.

4. Initial Requests for Nurse Waiver.--The first time that a nursing facility applies for a waiver, the State conducts an onsite survey before they may grant a waiver. The purpose of the survey is to establish that the waiver will not endanger the health and safety of residents. A full survey is not required. However, the survey must be of sufficient scope to ensure that the granting of the waiver will not endanger the health and safety of the residents.

While the acuity of illness of skilled nursing facility level residents makes an onsite visit desirable to confirm that the facility actually meets the requirements for a nurse staffing waiver, it is not required. The waiver determination may be made based on documentation of these requirements submitted by the skilled nursing facility.

B. Waiver of Life Safety Code (LSC).--(See '2472.)

C. Variations of Patient Room Size and/or Beds Per Room.--Resident rooms may have no more than four beds per room and must afford a minimum of 80 square feet per bed in multi-patient rooms. Single rooms must measure at least 100 square feet. 42 CFR 483.70(d)(3) states that variations may be permitted in individual cases where the facility demonstrates in writing that the variations are in accordance with the special needs of the residents and will not adversely affect their health and safety. A variation is construed to mean a waiver. The regional office has jurisdiction to approve such waivers or variances. The State has jurisdiction to approve them in Medicaid-only cases.

D. Documentation to Support Waivers or Variations.--The State should place an asterisk to the left of the data tag item on the Statement of Deficiencies, Form HCFA-2567, and include the required documentation to support the recommendation with the certification packet. For a nurse staffing waiver, the State enters a "W" in the plan of correction field in the Online Survey, Certification and Reporting System for the waived requirement.

Survey Process

7200. EMPHASIS, COMPONENTS, AND APPLICABILITY

Skilled nursing facilities and nursing facilities must be in compliance with the requirements in 42 CFR Part 483, Subpart B to receive payment under Medicare or Medicaid. To certify a skilled nursing facility or nursing facility, complete at least:

- A life safety code survey; and
- A standard survey (Forms HCFA-670, 671, 672, 677, 801 through 807, and Exhibits 85, 86, 88 to 95).

Follow the procedures in Appendix P for conducting all surveys of skilled nursing facilities and nursing facilities, whether freestanding, distinct parts, or dually participating. Do not use these procedures for surveys of intermediate care facilities for the mentally retarded (ICFs/MR), swing-bed hospitals, or skilled nursing sections of hospitals that are not separately certified as skilled nursing facility distinct parts.

Listed below are the long term care facility survey tasks for easy reference. See Appendix P for detailed guidance.

- Task 1 - Offsite Survey Preparation
- Task 2 - Entrance Conference/Onsite Preparatory Activities

- o Task 3 - Initial Tour
- o Task 4 - Sample Selection
- o Task 5 - Information Gathering

  A - General Observations of the Facility
  B - Kitchen/Food Service Observation
  C - Resident Review
  D - Quality of Life Assessment
  E - Medication Pass
  F - Quality Assessment and Assurance Review
  G - Abuse Prohibition Review

- o Task 6 - Information Analysis for Deficiency Determination

  A - Determination of Substandard Quality of Care

- o Task 7 - Exit Conference

7201. SURVEY TEAM SIZE AND COMPOSITION - LENGTH OF SURVEY

A. Survey Team Size.--Survey team size will vary, depending primarily on the size of the facility being surveyed. The State (or, for Federal teams, the regional office) decides how many members will be on the team. Survey team size is normally based upon the following factors:

- o The bed size of the facility to be surveyed;
- o Whether the facility has a historical pattern of serious deficiencies or complaints;
- o Whether the facility has special care units; and
- o Whether new surveyors are to accompany a team as part of their training.

B. Team Composition.--The State (or, for Federal teams, the regional office) decides what the composition of the survey team will be, as long as certain statutory and regulatory requirements are met. Sections 1819(g)(2)(E) and 1919(g)(2)(E) of the Act and 42 CFR 488.314 require that:

- o Skilled nursing facility and nursing facility standard surveys be conducted by a multidisciplinary team of professionals, at least one of whom must be a registered nurse;
- o Surveyors be free of conflicts of interest (see '7202 below); and
- o Surveyors successfully complete a training and testing program in survey and certification techniques that has been approved by the Secretary. In other words, surveyors must successfully complete the HCFA-approved training and pass Module A of the Surveyor Minimum Qualifications Test. Surveyors who assess the requirements of quality of care, nutritional dietary services, and drug therapy must also successfully complete Module B of the Surveyor Minimum Qualifications Test. (See '4009.1 of this manual for additional information concerning Surveyor Minimum Qualifications Test requirements.)

Within these parameters, the States (or, for Federal teams, the regional offices) are free to choose the composition of each team, and it is the State that determines what constitutes a professional. However, HCFA offers the following guidance:

o The State or regional office should consider using more than one registered nurse on teams that will be surveying a facility known to have a large proportion of residents with complex nursing or restorative needs.

o Because of the strong emphasis on resident rights, the psychosocial model of care, and rehabilitative aspects of care in the regulations and the survey process, the team should include social workers, registered dietitians, pharmacists, activity professionals, or rehabilitation specialists, when possible.

o It is important, to the extent practical, to utilize team members with clinical expertise and knowledge of current best practices that correspond to the resident population's assessed needs, the services rendered in the facility to be surveyed, and the type of facility to be surveyed. For example, if the facility has a known problem in dietary areas, there should be an effort to include a dietitian on the team; if a known problem in quality of life, a social worker. If the facility specializes in the care of residents with post trauma head injuries and strokes, a physical therapist may be included on the team.

o In addition to members of individual disciplines routinely included as members of the survey team, consideration should be given to the use of individuals in specialized disciplines who may not routinely participate as team members. These individuals would be available to assist the survey team when specific problems or questions arise. Consultants in these suggested disciplines include, but are not limited to, physicians, physician assistants, nurse practitioners, physical, speech, and occupational therapists, dieticians, sanitarians, engineers, licensed practical nurses, social workers, pharmacists, and gerontologists.

o In order to comply with the requirement that "No individual shall serve as a member of a...team [surveying a SNF or NF] unless the individual has successfully completed [the HCFA-approved] training and testing program," surveyors in training, i.e., those who have not successfully completed the required training, must be accompanied on-site by a surveyor who has successfully completed the required training and testing. While it is desirable that all survey team members be fully qualified, HCFA recognizes that trainees must be given opportunities to perform survey functions so that they can achieve "fully qualified" status. Participation in actual surveys is a valuable and integral part of a training program. In fact, in the orientation program designed for newly employed surveyors, HCFA recommends that 3 weeks be spent in the field as part of the training.

C. Length of Survey.--The length of a standard survey in terms of person hours is expected to vary, based on the size and layout of the facility and the number and complexity of concerns that need to be investigated onsite.

7202. CONFLICTS OF INTEREST FOR FEDERAL AND STATE EMPLOYEES

A. Introduction.--Conflicts of interest may arise within the Medicare/Medicaid certification when public employees' duties give them the potential for private gain (monetary or otherwise) or the opportunity to secure unfair advantages for outside associates. The same should be required of State employees whose positions may produce possible conflicts of interest. This includes all State surveyors and their supervisors. There are a number of Federal and State laws setting forth criminal penalties for abuses of privileged information, abuses of influence, and other abuses of public trust.

Federal employees are required to make a declaration of any outside interests and to update it whenever such interests are acquired. The same should be required of State employees whose positions may produce possible conflicts of interest. Both HCFA and the State are responsible for evaluating the need for preventive measures to protect the integrity of the certification program. When certification work is performed by agencies other than HCFA or the State, the State administrators and the subagency administrators have a shared responsibility for this surveillance.

In the case of States, it is not necessary to inform HCFA of all potential conflict situations. However, if an overt abuse requires corrective action, the regional office must be informed as described in '7202.

B. Conflicts of Interest.--

1. Prima Facie Conflicts of Interest.--Under 42 CFR 488.314(a)(4), any of the following circumstances disqualifies a surveyor for surveying a particular skilled nursing facility or nursing facility:

a. The surveyor currently works, or, within the past 2 years, has worked as an employee, as employment agency staff at the facility, or as an officer, consultant, or agent for the facility to be surveyed;

b. The surveyor has any financial interest or any ownership interest in the facility. (Indirect ownership, such as through a broad based mutual fund, does not constitute financial or ownership interest for purposes of this restriction.);

c. The surveyor has an immediate family member who has a relationship with a facility described in §7202. An immediate family member is defined in 42 CFR 488.301.; or

d. The surveyor has an immediate family member who is a resident in the facility.

2. Examples of Potential Conflicts of Interest.--HCFA and the States must consider all relevant circumstances that may exist beyond the benchmarks given in §7202 to ensure that the integrity of the survey process is preserved. For example, a surveyor may not have worked for the facility to be surveyed for more than 2 years, but may have left the facility under unpleasant circumstances, or, may not currently have an immediate family member who resides there, but may have recently had one residing there who the surveyor considers to have received inadequate care.

The following are typical of situations which may raise a question of possible conflicts of interest for Federal or State employees of an agency representing the Medicare/Medicaid survey and certification program. However, they do not necessarily constitute conflicts of interest.

a. Participation in ownership of a health facility located within the employing State;

b. Service as a director or trustee of a health facility;

c. Service on a utilization review committee;

d. Private acceptance of fees or payments from a health facility or group of health facilities or association of health facility officers for personal appearances, personal services, consultant services, contract services, referral services, or for furnishing supplies to a health facility;

e. Participation in a news service disseminating trade information to a segment of the health industry; and

f. Having members of one's immediate family engaged in any of the above activities.

C. Report and Investigation of Improper Acts.--Any acts of employees in violation of Federal or State laws or regulations regarding conflicts of interest should be handled in accordance with applicable Federal or State procedures. In the case of State employees, conflicts of interest violations must be reported to the regional office, and the regional office must be kept advised of the corrective

actions. States should ask for assistance or advice in the case of any impropriety involving a conflict of interest which cannot be handled immediately under an applicable State procedure. The regional office of the Inspector General, along with the HCFA regional office, will then work in close cooperation with the responsible State officials until the matter is resolved.

7203. SURVEY PROTOCOL

A. Introduction.--This protocol is established pursuant to "1819(g)(2)(C) and 1919(g)(2)(C) of the Act to provide guidance to surveyors conducting surveys of long term care facilities participating in the Medicare and Medicaid programs. The protocol consists of survey procedures, worksheets, and interpretive guidelines. It serves to explain and clarify the requirements for long term care facilities and is required to be used by all surveyors measuring facility compliance with Federal requirements. The purpose of this protocol is to provide suggestions, interpretations, check lists, and other tools for use both in preparation for the survey and when performing the survey onsite.

The interpretive guidelines merely define or explain the relevant statutes and regulations and do not impose any additional costs or place other burdens on any health care facility. (See '2712.)

B. Initial Certification Surveys.--All initial surveys must verify substantial compliance with all the regulatory requirements contained in 42 CFR 483.5 through 42 CFR 483.75. Follow Appendix P, Survey Protocol for Long Term Care Facilities.

If distinct part status is at issue, determine whether the facility meets the criteria for certification as a distinct part. (See "2110 and 2112.)

C. Resurvey of Participating Facilities.--Follow the procedures specified in Appendix P for standard and extended surveys.

D. Post Survey Revisit (Follow-up).--When the State has cited deficiencies during the course of a survey, the survey agency conducts a post survey revisit, as necessary, to determine if the facility now meets the requirements for participation.

E. Abbreviated Standard Survey.--This survey focuses on particular tasks that relate, for example, to complaints received, or a change of ownership, management, or Director of Nursing. It does not cover all the aspects covered in the standard survey, but rather concentrates on a particular area of concern(s). The survey team (or surveyor) may investigate any area of concern and make a compliance decision regarding any regulatory requirement, whether or not it is related to the original purpose of the survey complaint.

1. Complaint Investigations.--If the State's review of a complaint allegation(s) concludes that one or more violations of requirements may have occurred, and only a survey can determine whether a deficiency(ies) exist, conduct a standard or abbreviated standard survey. (See Appendix P.)

2. Substantial Changes in a Facility's Organization and Management.--If a facility notifies you of a change in organization or management, review the change to ensure compliance with the regulations. Request copies of the appropriate documents, e.g., written policies and procedures, personnel qualifications and agreements, if they were not submitted. If changes in a facility's organization and management are significant and raise questions of its continued substantial compliance, determine, through a survey, whether deficiencies have resulted. Collect information about changes in the facility's organization and management on the Medicare and other Federal Care Program General Enrollment Form HCFA-855.

F. Extended Survey/Partial Extended Survey.--If, as a result of its findings during the standard survey, the team suspects substandard quality of care as defined in 42 CFR 488.301, it expands the standard survey. If substandard quality of care is verified, this expanded survey is considered to be an extended (or partial extended survey). (See Appendix P.)

7205. SURVEY FREQUENCY

A. Introduction.--The survey and certification provisions set forth in §§'1819(g)(2)(A)(iii) and 1919(g)(2)(A)(iii) of the Act and in 42 CFR 488.308 require that each skilled nursing facility and nursing facility be subject to a standard survey no later than 15 months after the last day of the previous standard survey and that the statewide average interval between standard surveys of skilled nursing facilities and nursing facilities not exceed 12 months.

B. Scheduling and Conducting Surveys.--The State completes a standard survey of each skilled nursing facility and nursing facility not later than 15 months after the previous standard survey.

Facilities with poor histories of compliance may be surveyed more frequently to ensure that residents are receiving quality care in a safe environment.

Facilities with excellent histories of compliance may be surveyed less frequently to determine compliance, but no less frequently than every 15 months.

1. Changes That May Prompt Survey.--If the State suspects that a change of ownership, management firm, administrator, or Director of Nursing may have caused a decline in the quality of care furnished by a skilled nursing facility or nursing facility, it may conduct a standard or abbreviated standard survey within 60 days of the change.

2. Frequency.--The State may conduct surveys as frequently as necessary to determine if a facility complies with the participation requirements and to also determine if the facility has corrected any previously cited deficiencies.

3. Conducting Complaint Surveys.--Refer to complaint investigation procedures in "7700 and 7702, and Appendix P.

C. Determining Standard Survey Interval for Each Facility.--The standard survey interval for each facility (which may not exceed 15 months) is calculated as follows:

o The number of days between the completion of the health portions of the current and last standard survey is divided by 31 to determine the number of months between standard surveys for each provider;

o The last day of the health portion of the standard survey, not the last day of the entire health and life safety code survey, is the date used to calculate the interval.

EXCEPTION: In the case of immediate jeopardy found on a life safety code survey, the last day of the life safety code survey is used as the date of survey for the purpose of remedy imposition and/or termination time frames, but NOT for the calculation of the survey frequency interval. The last day of observations used in determining compliance or noncompliance with Federal participation requirements is the last day of the standard health survey. For example, if the survey team makes survey observations on days 1, 2, and part of 3, and also performs the exit conference on day 3, day 3 would be the last day of the standard health survey. However, if the survey team performs the same survey but holds the exit conference several days later, the last day of the standard health survey would be the last workday of observations at the facility (i.e., day 3), not the exit conference date;

o If an extended survey begins because substandard quality of care is identified during the health portion of a standard survey, the last day of the health portion of the standard survey is used to calculate the survey frequency requirements. The date of the extended survey is not used in calculating the survey interval or statewide average requirements;

o Abbreviated standard surveys are not counted in the calculation. An abbreviated standard survey is a survey other than a standard survey to gather information on facility compliance with the requirements for participation primarily through resident-centered techniques. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or Director of Nursing; or other indicators of specific concern. (See 42 CFR 488.301.);

o When an abbreviated standard survey identifies factors which prompt the surveyors to decide to expand to a full standard survey, this full standard survey is counted in the calculation of the standard survey interval using the last date of the health portion of the standard survey as the survey date; and

o Revisits are not counted in the calculation of the standard survey interval.

Online Survey, Certification and Reporting System data is used to identify facilities that have not received a standard survey within 15 months.

Survey information for the fiscal year must be entered by November 15 of each year in order for Central Office to calculate the statewide average.

D. Assessing Compliance With Survey Frequency Requirements.--The statewide average interval for each State is available through the Online Survey, Certification and Reporting System, Report 27, Survey Frequency.

The regional office has the ongoing responsibility to monitor a State's compliance with the survey frequency requirements.

E. Actions to Ensure Compliance.--No action is necessary if the standard survey interval for a provider is not greater than 15 months and the statewide average is not greater than 12 months.

If the standard survey interval for a provider is greater than 15 months and/or the statewide average interval is greater than 12 months, the regional office will notify the State, determine if a problem exists, and take appropriate action. This action is specified in §7801.

7207. UNANNOUNCED SURVEYS

A. Introduction.--This instruction implements §§1819(g)(2)(A) and 1919(g)(2)(A) of the Act, and 42 CFR 488.307.

B. Standard Surveys Must Be Unannounced.--The State has the responsibility for keeping surveys unannounced and their timing unpredictable. This gives the State agency doing the surveying greater ability to obtain valid information. It remains HCFA's intention to extend this policy of not announcing standard surveys to not announcing any type of nursing home survey such as abbreviated or complaint surveys. Therefore, if HCFA conducts standard surveys or validation surveys, the regional office must follow the same procedures as required of the States to not announce surveys. The only exceptions to this policy would be if, for instance, some additional documentation was required and the most efficient way to obtain it would be through making an appointment and revisiting the facility or asking that it be provided via electronic means. The State should notify the State ombudsman's office according to the protocol developed between the State and the State ombudsman's office. This protocol must ensure strict confidentiality concerning the survey dates. (See Appendix P.)

To increase the opportunity for unpredictability in standard surveys, the State survey agencies and Federal surveyors should incorporate the following procedures when planning facility surveying:

1. Nonsequential Order.--Facilities, within a given geographical area, should not be surveyed in the same order as was conducted in the previous standard survey;

2. Variance in Timing (Time of Day, Day of Week, Time of Month).--When facilities are surveyed, the time of day, day of the week, and time of month should be varied from the time of the previous standard survey. The time of day that surveyors begin should extend beyond the business hours of 8:00 a.m. to 6:00 p.m. and should either incorporate evening hours after 7:00 p.m. or morning hours before 7:00 a.m. In addition, the day of the week should vary to include weekend days, Saturday, and Sunday. At least ten percent of surveys must begin either on the weekend or in the evening/early morning hours. Likewise, the month in which a survey begins should not, if possible, coincide with the month in which the previous standard survey was conducted. For example, unannounced standard surveys could begin at:

- o 7:30 p.m. on a Monday evening in early July (previous standard survey occurred early June);
- o 6:00 a.m. on a Wednesday morning and survey continues through the weekend until it is completed; or
- o 11:00 a.m. on a Saturday morning.

In addition, standard surveys that are conducted to satisfy the ten percent requirement must be conducted on consecutive days. Consecutive days mean calendar days and are to include Saturdays, Sundays, and Holidays. For example, beginning a survey at 8:00 a.m. on a Saturday morning must be continued until its completion through the weekend and into the following week.

NOTE: If there are situations that arise and the State determines that a standard survey cannot be conducted on consecutive days, the State must contact the regional office and obtain approval prior to the commencement of the standard survey or within reasonable time after the initial start day.

C. HCFA Review of State Scheduling Procedures.--The regional office reviews annually each of its State's procedures for assuring that nursing home surveys are not announced through the methods by which they are scheduled or conducted.

D. Imposition of Civil Money Penalties.--If any individual has, in any way, given prior notification to a facility of the date of a standard survey, the State or HCFA is to contact the regional Office of the Inspector General and report the name of the individual and what has occurred. The Office of the Inspector General will further investigate and make a determination as to whether or not a Federal civil money penalty will be imposed. A civil money penalty of up to $2000 may be imposed under "1819(g)(2)(A)(I) and 1919(g)(2)(A)(I) of the Act. The provisions of '1128A of the Act apply to civil money penalties. The imposition of a civil money penalty applies only when a standard survey is announced. See 42 CFR Part 1005 for policy developed by the Office of the Inspector General regarding administrative appeals of Federal civil money penalties.

E. Withdrawal of Nurse Aide Training and Competency Evaluation Program.-- If a facility refuses to permit an unannounced State visit, 42 CFR 483.151(e)(3) requires the State to withdraw approval of a nurse aide training and competency evaluation program or a nurse aide competency evaluation program for that facility.

7210. SUBSTANDARD QUALITY OF CARE AND EXTENDED AND PARTIAL EXTENDED SURVEYS

A. Introduction.--This section is established pursuant to §§1819(g)(2)(B) and 1919(g)(2)(B) of the Act and 42 CFR 488.310 to provide guidance to surveyors in conducting an extended or partial extended survey. The only time an extended or partial extended survey is conducted is when substandard quality of care is identified. This section also explains notice requirements as required in §§1819(g)(5)(C) and 1919(g)(5)(C) of the Act and 42 CFR 488.325, disclosure of results of surveys and activities, when substandard quality of care is found. This section discusses the consequences to a nurse aide training and competency evaluation program when an extended or partial extended survey is conducted. (See §7001 for definition of substandard quality of care .)

B. Expansion of the Survey.--When the State or regional office conducts a standard survey or abbreviated standard survey and suspects substandard quality of care but does not have sufficient information to confirm or refute the substandard quality of care , the survey may be expanded. (See Appendix P and §7210.) This expansion of the standard or abbreviated standard survey does not necessarily constitute an extended survey.

If the expanded survey does not identify substandard quality of care but finds noncompliance, the State or regional office prepares Form HCFA-2567 and follows the procedures required in §7305.

If the expanded survey verifies substandard quality of care , the State or regional office conducts an extended survey, including the components specified in subsection C or a partial extended survey including the components specified in subsection D.

C. Elements Reviewed.--The State or regional office, in extending the standard survey, must include the following:

1. Review a larger sample of resident assessments than the sample used in a standard survey;

2. Review the staffing and in-service training;

3. If appropriate, examine consultant contracts;

4. Review the policies and procedures related to the requirements for which deficiencies exist;

5. Review and verify compliance with 42 CFR 483.30, nursing services; 42 CFR 483.40, physician services; and 42 CFR 483.75, administration; and

6. Investigate any participation requirement at the discretion of the surveying entity.

D. Finding Substandard Quality of Care on an Abbreviated Standard Survey.--If on an abbreviated standard survey the State or regional office identifies substandard quality of care , the survey team must review the policies and procedures related to the requirements for which deficiencies exist and must perform other tasks listed in subsection C. The State or regional office could also conduct a standard survey in addition to the extended survey described above.

E. Time Frames.--An extended or partial extended survey should be conducted immediately after the standard or abbreviated standard survey, but, if delayed, not later than 14 calendar days after completion of a standard survey or abbreviated standard survey which found that the facility had furnished substandard quality of care .

F. Notices.--When substandard quality of care is identified as a result of a standard or abbreviated standard survey, an extended or partial extended survey is conducted. In addition to the notices required of all surveys in '7300, the State must issue notices to the following:

o The State board responsible for the licensing of the nursing home administrator; and

o The attending physician of each resident who was identified as having been subject to substandard quality of care. (See §7320.)

According to 42 CFR 488.325, disclosure of results of surveys and activities, the facility is responsible for submitting to the State the names of the attending physician for each resident who was identified as having been subject to substandard quality of care , regardless of whether payment is made through Medicare, Medicaid, or private pay. (See §7905.)

G. Nurse Aide Training and Compentency Evaluation Program.--As required in §§1819(f)(2)(B)(iii)(I)(b) and 1919(f)(2)(B)(iii)(I)(b) of the Act, the Nurse aide training and compentency evaluation program must be denied or withdrawn when an extended or partial extended survey is conducted. (See '7809 for specific procedures.)

7212. INFORMAL DISPUTE RESOLUTION

A. Introduction.--42 CFR 488.331 requires that HCFA and the States, as appropriate, offer skilled nursing facilities, nursing facilities, and skilled nursing facilities/nursing facilities an informal opportunity to dispute cited deficiencies upon the facility's receipt of the official Form HCFA-2567. A State does not need to create any new or additional processes if its existing process meets the requirements described in subsection C. The informal dispute resolution process, as established by the State or HCFA regional office, must be in writing so that it is available for review upon request.

B. Purpose.--The purpose of this informal process is to give providers one opportunity to refute cited deficiencies after any survey.

C. Mandatory Elements of Informal Dispute Resolution.--The following elements must be included in each Informal dispute resolution process offered:

1. Upon their receipt of the official Form HCFA-2567, facilities must be offered one informal opportunity, if they request it, to dispute deficiencies with the entity that conducted the survey.

2. Facilities may not use the informal dispute resolution process to delay the formal imposition of remedies or to challenge any other aspect of the survey process, including the:

o Scope and severity assessments of deficiencies with the exception of scope and severity assessments that constitute substandard quality of care or immediate jeopardy;

o Remedy(ies) imposed by the enforcing agency;

o Alleged failure of the survey team to comply with a requirement of the survey process;

o Alleged inconsistency of the survey team in citing deficiencies among facilities; or

o Alleged inadequacy or inaccuracy of the informal dispute resolution process.

3. Facilities must be notified of the availability of informal dispute resolution in the letter transmitting the official Form HCFA-2567. (See Exhibit 139 for transmission of Form HCFA-2567.) Notification of this process should inform the facility:

o That it may request the opportunity for informal dispute resolution, and that if it requests the opportunity, the request must be submitted in writing along with an explanation of the specific deficiencies that are being disputed. The request must be made within the same 10 calendar day period the facility has for submitting an acceptable plan of correction to the surveying entity;

o Of the name, address, and telephone number of the person the provider must contact to request informal dispute resolution;

o How informal dispute resolution may be accomplished in that State, e.g., by telephone, in writing, or in a face-to-face meeting.

o Of the name and/or the position title of the person who will be conducting the informal dispute resolution, if known.

4. Failure to complete informal dispute resolution timely will not delay the effective date of any enforcement action against the facility.

5. When a provider is unsuccessful during the process at demonstrating that a deficiency should not have been cited, the surveying entity must notify the facility in writing that he/she was unsuccessful.

6. When a facility is successful during the informal dispute resolution process at demonstrating that a deficiency should not have been cited:

o The deficiency citation should be marked "deleted," signed, and dated by a supervisor of the surveying entity;

o Any enforcement action(s) imposed solely because of that deficiency citation should be rescinded; and

o Adjust the scope and severity assessment, if necessary, to reflect the outcome of informal dispute resolution, e.g., elimination of deficiencies.

NOTE: The facility has the option to request a clean (new) copy of the Form HCFA-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form HCFA-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Any Form HCFA-2567 and/or plan of correction that is revised or changed as a result of informal dispute resolution must be disclosed to the ombudsman in accordance with '7904.

Cited deficiencies should not be entered into the Online Survey, Certification and Reporting System/Online Data Input and Edit, nor posted to the Nursing Home Compare Website while informal dispute resolution is pending.

7. Regardless of whether or not a facility has already used the one opportunity for informal dispute resolution, the following table indicates when another opportunity for informal dispute resolution would be appropriate, if requested by the facility, based on the results of a revisit or of informal dispute resolution:

Results of Revisit or of Informal Dispute Resolution	Eligibility for Informal Dispute Resolution
Continuation of same deficiency at revisit.	Yes
New deficiency (i.e., new or changed facts, new tag) at revisit or as a result of an informal dispute resolution.	Yes
New example of deficiency (i.e., new facts, same tag) at revisit or as a result of an informal dispute resolution.	Yes
Different tag but same facts at revisit or as a result of an informal dispute resolution.	No, unless the new tag constitutes substandard quality of care.

NOTE: A second informal dispute resolution is not offered on the existence of the deficiency(ies) as of the date of the first survey.

8. Written description of the surveying entity's informal dispute resolution process must be made available to a facility upon the facility's request.

9. States are encouraged to include in the informal dispute resolution process at least one person as part of the decision making process who was not directly involved in the survey. This may include, but is not limited to, another surveyor, ombudsman, a member of another survey team, etc.

D. Additional Elements for Federal Informal Dispute Resolution.--In addition to those elements cited in subsection C, HCFA has adopted the following elements to be incorporated in all cases involving deficiencies cited as a result of Federal surveys. They are designed to clarify and expedite the resolution process. States are free to incorporate these elements into their procedures.

1. Notice to the facility will indicate that the informal dispute resolution, including any face-to-face meetings, constitutes an informal administrative process that in no way is to be construed as a formal evidentiary hearing.

2. Notice to the facility will indicate that it may be accompanied by counsel if there is a face-to-face meeting. If it chooses to be accompanied by counsel, then it must indicate that in its request for informal dispute resolution, so that HCFA may also have counsel present.

3. HCFA will verbally advise the facility of HCFA's decision relative to the informal dispute, with written confirmation to follow.

7300. CERTIFICATION OF COMPLIANCE AND NONCOMPLIANCE FOR SKILLED NURSING FACILITIES AND NURSING FACILITIES

A. Introduction.--These procedures are established pursuant to §1819(g) and 1919(g) of the Act and 42 CFR 488.330 to provide guidance as to when the State or the regional office has the responsibility for certifying compliance or noncompliance and what procedures to follow. This section also defines the concept of "substantial compliance" for certification purposes.

The State has the responsibility for certifying a skilled nursing facility's or nursing facility's compliance or noncompliance, except in the case of State-operated facilities. However, the State's certification for a skilled nursing facility is subject to HCFA's approval. "Certification of compliance" means that a facility's compliance with Federal participation requirements is ascertained. In addition to certifying a facility's compliance or noncompliance, the State recommends appropriate enforcement actions to both the State Medicaid agency for Medicaid and the regional office for Medicare. In some cases, the State recommends and, as authorized by the regional office, carries out the imposition of category 1 remedies, as well as the denial of payment for new admissions remedy. As specified in 42 CFR 488.10, the regional office, determines a facility's eligibility to participate in the Medicare program based on the State's certification of compliance and a facility's compliance with civil rights requirements.

Throughout this chapter, references are made to the State Medicaid agency in taking enforcement actions against a Medicaid provider. However, there is nothing in this Federal regulation which precludes the State Medicaid agency from delegating the authority to act on its behalf in imposing enforcement remedies for Medicaid nursing facilities. The regional office has the responsibility for certifying a State-operated skilled nursing facilities or nursing facilities compliance or noncompliance. In accordance with '1919(h)(3), the regional office may take independent and binding enforcement action against any nursing facility based on its findings of noncompliance. However, the regional office=s certification is usually based on the State's survey and the resultant findings.

B. Survey and Certification Responsibility.--Except as specified in '7300 the following entities are responsible for surveying and certifying a skilled nursing facility=s or nursing facility=s compliance or noncompliance with Federal requirements.

o State-Operated Skilled Nursing Facilities or Nursing Facilities or State-Operated Dually Participating Facilities.--The State conducts the survey, but the regional office certifies compliance or noncompliance and determines whether a facility will participate in the Medicare or Medicaid programs.

o Non-State Operated Skilled Nursing Facilities.--The State conducts the survey and certifies compliance or noncompliance, and the regional office determines whether a facility is eligible to participate in the Medicare program.

o Non-State Operated Nursing Facilities.--The State conducts the survey and certifies compliance or noncompliance. The State's certification is final. The State Medicaid agency determines whether a facility is eligible to participate in the Medicaid program.

o Non-State Operated Dually Participating Facilities (Skilled Nursing Facilities/Nursing Facilities).--The State conducts the survey and certifies compliance or noncompliance. The State's certification of compliance or noncompliance is communicated to the State Medicaid agency for the nursing facility and to the regional office for the skilled nursing facility. In the case where the State and the regional office disagree with the certification of compliance or noncompliance, see §7807 for rules to resolve such disagreements.

C. Initial Survey and Certification Responsibility.--The State determines whether a prospective provider is in substantial compliance with the nursing home participation requirements. If the provider is in substantial compliance, the State certifies and recommends that the regional office and/or State Medicaid agency enter into an agreement with the provider. If the provider is not in substantial compliance, the State recommends that the regional office and/or State Medicaid agency deny participation. The regional office and/or State Medicaid agency sends the letter notifying the facility of its denial of participation in the Medicare and/or Medicaid programs, and includes the appeal rights available under 42 CFR 431.153 and 42 CFR 498.3(b).

D. Effect of HCFA's Validation Authority.--The regional office may make independent findings of compliance or noncompliance based on its own validation survey. The regional office's finding of noncompliance is binding and takes precedence over the State's certification of compliance based on the State's survey.

The regional office may also make independent findings of compliance or noncompliance based on its review of the State's certification of compliance or noncompliance. The regional office need not conduct an onsite visit in order to exercise its validation authority. However, the regional office's determination of compliance based on the State's findings which had resulted in the State's certification of noncompliance does not take precedence. (See §7807 for resolving disagreements between the regional office and the State.)

7301. ACTION WHEN FACILITY IS NOT IN SUBSTANTIAL COMPLIANCE

A. Immediate Jeopardy Exists (see §7307.)--When immediate jeopardy exists:

1. The regional office or State Medicaid agency will impose termination and/or temporary management in as few as 2 calendar days (one of which must be a working day) after the survey which determined immediate jeopardy. In all cases of immediate jeopardy, the provider agreement must be terminated by HCFA or State Medicaid agency no later than 23 calendar days from the last day of the survey if the immediate jeopardy is not removed.

2. The regional office or State Medicaid agency should impose another remedy in addition to termination when immediate jeopardy has been determined. An alternative remedy should be considered without first offering the facility an opportunity to correct, even if the facility successfully removes the immediate jeopardy but is still not in substantial compliance.

3. The regional office or State Medicaid agency may impose a civil money penalty between $3,050 and $10,000 per day of immediate jeopardy. It will be effective as of the date the immediate jeopardy began which is usually the date first identified. As an alternative, the regional office or State Medicaid agency may impose a Aper instance@ civil money penalty from $1,000 to $10,000 for each deficiency. However, the aggregate for the survey cannot exceed $10,000 per day.

4. The regional office or State Medicaid agency may impose other remedies as described in '7500. Except for State monitoring which requires no notice, the regional office or State Medicaid agency may impose the remedies 2 calendar days (one of which must be a working day) from the date the provider receives notice.

5. The regional office, State Medicaid agency, or State (as authorized by HCFA) may impose State monitoring immediately.

6. The State, as authorized by HCFA, may also impose denial of payment for new admissions effective 2 calendar days (one of which must be a working day) from the date the provider receives notice.

7. The State will require that the facility submit an allegation that the immediate jeopardy has been removed and sufficient detail to demonstrate how the immediate jeopardy has been addressed so that the State can verify onsite the removal of the immediate jeopardy. A plan of correction should be deferred until the facility has successfully demonstrated removal of immediate jeopardy. Facilities should be cautioned that the allegation of removal of the immediate jeopardy does not guarantee a revisit before the effective date of termination.

8. The State will require a plan of correction for all deficiencies cited once the immediate jeopardy removal visit has been completed.

B. Immediate Jeopardy Does Not Exist (See §7310).--When immediate jeopardy does not exist:

1. HCFA or the State must determine whether the facility will be given an opportunity to correct its deficiencies before remedies are imposed in accordance with §7304 .

2. The regional office or State Medicaid agency should impose another remedy in addition to termination for a facility not being given an opportunity to correct.

3. The regional office or State Medicaid agency terminates the Medicare and/or Medicaid provider agreements that are in effect no later than 6 months from the date of survey which determined noncompliance as described in '7600 if the noncompliance persists for 6 months from the last day of the survey during which it was originally identified. Except for State monitoring for which no notice is required, the regional office or State Medicaid agency may impose these remedies 15 calendar days from the date the facility receives notice.

4. When there is an opportunity to correct before remedies are imposed, the State will request an acceptable plan of correction, provide formal notice of the imposition of denial of payment for new admissions and subsequent termination if compliance is not achieved, conduct a revisit, and recommend any other remedies if noncompliance remains at the time of the revisit.

5. The regional office or State Medicaid agency must impose denial of payment for new admissions no later than 3 months after the last day of the survey that identified the noncompliance if substantial compliance is not achieved.

6. The regional office or State Medicaid agency (or State, as authorized by HCFA) may impose State monitoring without notice.

7. The regional office or State Medicaid agency may impose either a per day civil money penalty, effective as of the date the noncompliance began, which is usually the day it was first identified, or a Aper instance@ civil money penalty. The civil money penalty may be assessed for past noncompliance, for days of noncompliance after the finding is made, or a combination thereof. The regional office or State Medicaid agency determines the amount of the civil money penalty.

8. The State may impose, as authorized by the regional office or State Medicaid agency, category 1 remedies and/or denial of payment for new admissions. (See §7310.)

C. Prospective Providers.--If a prospective provider is not in substantial compliance, the regional office or State Medicaid agency must deny participation in the Medicare and Medicaid programs.

7303. APPEAL OF CERTIFICATION OF NONCOMPLIANCE

With the exception of State monitoring, facilities may appeal the finding of noncompliance which led to an enforcement action. Enforcement action includes termination, alternative remedies included in '7400, and any alternative or additional State remedies. Rather than send an appeal to the regional office, facilities may appeal directly to the Departmental Appeals Board in the Office of the Secretary, Health and Human Services, with a copy to the State and regional office. However, in the case of an enforcement action taken by the State against a Medicaid-only facility, the appeal should be sent to the State. The appeal procedures for facilities are found at:

- 42 CFR Part 498 for State-operated skilled nursing facilities, nursing facilities or skilled nursing facilities/nursing facilities;

- 42 CFR Part 498 for non-State operated skilled nursing facilities or skilled nursing facilities/nursing facilities, and non-State nursing facilities in which the regional office disagrees with the State's finding of compliance; and

- 42 CFR Part 431 for non-State operated nursing facilities in which the determination was made by the State Medicaid agency or was subject to a validation by the regional office and the regional office agrees with the State's finding.

With the exception of civil money penalties, enforcement actions may be imposed while the facility is appealing the noncompliance which led to the enforcement action. For example, a facility could have its provider agreement terminated effective May 1, while the hearing of the facility's appeal may not occur until after that date. Except in the case of civil money penalties, a request for a hearing will not defer the effective date of the enforcement action. Further, in accordance with 42 CFR 431.153(e)(2), a nursing facility's request for a hearing on denial or termination does not delay the enforcement action and need not be completed before the effective date of the action. In the case of civil money penalties, the hearing, if requested, must be completed before the civil money penalty can be collected. However, the daily civil money penalty amount continues to accrue from the effective date until the facility is either terminated or has achieved substantial compliance.

In accordance with 42 CFR 498.40(b), the content of the request for a hearing must identify the specific issues, and the findings of fact and conclusions of law with which the facility disagrees, and specify the basis for contending that the findings and conclusions are incorrect.

7304. CERTIFICATION-RELATED TERMS

An opportunity to correct deficiencies before remedies are imposed is not assured. HCFA or the State has no obligation to give a provider an opportunity to correct deficiencies prior to imposing remedies. HCFA and the State must only meet the minimum notice requirements that are applicable to the imposition of remedies. HCFA's policy about when providers with deficiencies are given an opportunity to correct deficiencies before remedies are imposed, is as follows:

A. Opportunity to Correct Deficiencies Before Remedies are Imposed--At HCFA's or the State's discretion, facilities may be given an opportunity to correct before remedies are imposed when they do not meet the criteria in this section for no opportunity to correct.

B. No Opportunity to Correct Deficiencies Before Remedies are Imposed--

1. Mandatory Criteria.--

o Facilities will not be given an opportunity to correct before remedies are imposed when they have deficiencies of actual harm or above on the current survey, and on the previous standard survey or any intervening survey (i.e., any survey between the current survey and the last standard survey). This is reflective of scope/severity levels of AG@ or above on the enforcement grid.

o Previously terminated facilities that have deficiencies causing actual harm on the first survey after re-entry into the program will not be given an opportunity to correct.

o Facilities that have immediate jeopardy will not be given an opportunity to correct. Removal of immediate jeopardy may, at HCFA',s discretion, result in rescission of a termination; it will not result in rescission of alternative remedies such as civil money penalties or denial of payment for new admissions.

o Noncompliance against which a per instance civil money penalty was imposed.

2. Additional State Discretion.--States have the discretion to establish additional guidelines for determining when facilities will be subject to immediate remedies with no prior opportunity to correct deficiencies.

C. Other Times When Facilities May Not be Given an Opportunity to Correct.--HCFA's or the States's discretion, facilities having noncompliance on the current survey, but not meeting criteria at 1. or 2. above, may also be subject to immediate sanctions. These facilities may not be provided a prior period to correct after consideration by HCFA or the State because of the following minimum factors:

o Scope and severity of the deficiency;

o A willingness and ability of the provider to correct the deficiency; and

o The effectiveness of the provider=s quality assurance and monitoring system to prevent recurrence of the deficiency.

D. Acceptable Plan of Correction.--All providers having deficiencies (other than those at scope and severity level A) must submit an acceptable plan of correction before substantial compliance can be determined. An acceptable plan of correction must:

1. Address how corrective action will be accomplished for those residents found to have been affected by the deficient practice;

2. Address how the facility will identify other residents having the potential to be affected by the same deficient practice;

3. Address what measures will be put into place or systemic changes made to ensure that the deficient practice will not recur;

4. Indicate how the facility plans to monitor its performance to make sure that solutions are sustained. The facility must develop a plan for ensuring that correction is achieved and sustained. This plan must be implemented, and the corrective action evaluated for its effectiveness. The plan of correction is integrated into the quality assurance system. At the revisit, the quality assurance plan is reviewed to determine the earliest date of compliance. If there is no evidence of quality assurance being implemented, the earliest correction date will be the date of the revisit; and

5. Include dates when corrective action will be completed. The corrective action completion dates must be acceptable to the State. If the plan of correction is unacceptable for any reason, the State will notify the facility in writing. If the plan of correction is acceptable, the State will notify the facility by phone, e-mail, etc. Facilities should be cautioned that they are ultimately accountable for their own compliance, and that responsibility is not alleviated in cases where notification about the acceptability of their plan of correction is not made timely. The plan of correction will serve as the facility's allegation of compliance.

In cases of non-immediate jeopardy, a plan of correction must be submitted within 10 calendar days from the date the provider receives its Form HCFA-2567. If an acceptable plan of correction is not received within 10 calendar days from the date the provider received its Form HCFA-2567, the State notifies the provider that it is recommending to the regional office and/or the State Medicaid agency that remedies be imposed effective as soon as notice requirements are met. This is because, in non-immediate jeopardy cases, the plan of correction serves as the facility's allegation of compliance and, without it, HCFA and the State have no basis on which to conduct a revisit to determine compliance.

In most cases of immediate jeopardy, the facility submits an allegation of removal of the immediate jeopardy and defers submission of a plan of correction until the immediate jeopardy has been removed. If this occurs, the allegation of removal of the immediate jeopardy must include the date the immediate jeopardy was removed, and sufficient detail demonstrating that the immediate jeopardy has been addressed. Once the removal of the immediate jeopardy is verified, the surveying entity will provide a Form HCFA-2567 to the facility, including the noncompliance which constituted immediate jeopardy, and request that a plan of correction be submitted within 10 calendar days.

E. Last Day of Survey.--For purposes of computing 3 months or 6 months from the finding of noncompliance, use the last day of the standard health survey on which the noncompliance was identified. When a Life Safety Code survey found the noncompliance, the clock still starts on the last day of the standard health survey. For purposes of the first notice of noncompliance, use the last day of the survey which found the noncompliance.

For example, if the State conducted a standard health survey on May 1 (which may or may not have found noncompliance), and then found noncompliance during a Life Safety Code survey 30 days after the health survey was conducted, the Form HCFA-2567 would be sent 10 days after the completion of the Life Safety Code survey. However, the mandatory denial of payment remedy at the end of the 3rd month would begin 3 months after the last day of the standard health survey, or May 1.

EXCEPTION: For purposes of sending notices, in immediate jeopardy situations, the last day of the survey begins with the survey which found the immediate jeopardy.

7305. NOTICE REQUIREMENTS

A. Initial Notices by Surveying Entity.--

1. Initial Notice.--When no immediate jeopardy exists and an opportunity to correct is provided before remedies are imposed, the surveying entity sends out an initial notice notifying the provider of the following. The State also sends a copy of this notice to the State Medicaid agency and regional office. The notice:

a. Transmits deficiencies cited (those listed on the Form HCFA-2567, as well as those isolated deficiencies which cause no harm and potential for only minimal harm);

b. Provides notice of the mandatory remedy which must be imposed if the provider fails to achieve substantial compliance at 6 months, (i.e., termination of provider agreement and consequent cessation of payments);

c. May provide that this notice serves as a formal notice of the imposition of denial of payment for new admissions and any category 1 remedies authorized by HCFA and/or the State Medicaid agency, to be effective on (date the State expects correction based on the facility's plan of correction) but in no case later than 3 months from the date of the survey if the provider fails to achieve substantial compliance;

d. Provides the date by which correction must be made which is reflected by the completion dates on the plan of correction;

e. Provides that the State=s proposed remedies will be forwarded to HCFA/State Medicaid agency if correction is not achieved at the first revisit. Civil money penalties will be effective as of the date that substantiated noncompliance began, usually the date of the survey. All other remedies will be imposed prospectively after 15 days notice. These imposed remedies, as authorized by HCFA and the State Medicaid agency, will take effect without further notice from the regional office or State Medicaid agency.

f. Provides that an acceptable plan of correction is required in response to deficiencies listed on the Form HCFA-2567. (See §7304.C.) The plan of correction will serve as the facility's allegation of compliance;

g. Informs of the opportunity for informal dispute resolution;

h. Specifies that if an acceptable plan of correction is not received within 10 calendar days, the State will notify the provider that it is recommending to the regional office and/or the State Medicaid agency that remedies other than category 1, and/or denial of payment for new admissions be imposed effective as soon as notice requirements are met. Formal notice of imposition of category 1 remedies and denial of payment for new admissions may already be officially provided in this initial notice, as authorized by HCFA and/or the State Medicaid agency;

i. Provides elements of an acceptable plan of correction. (See '7304D.)

j. Informs the facility of the loss of Nurse Aide Training and Competency Evaluation Program, and appeal rights if based on a finding of substandard quality of care, if applicable; and

k. Provides that when substandard quality of care is determined, the facility must provide a list of physicians for residents identified with substandard quality of care on the survey. The State must notify each physician and refer the administrator to the State=s licensing board.

2. Initial Notice--When no immediate jeopardy exists, and no opportunity to correct is provided before remedies are imposed, the surveying entity sends an initial notice which:

a. Transmits deficiencies cited on the HCFA-2567 (see 1.a);

b. Provides notice of the provider agreement termination that must be imposed if the provider has not achieved substantial compliance 6 months from the last day of the survey that found the noncompliance;

c. May provide that this notice serves as a formal notice of the imposition of denial of payment for new admissions and/or any category 1 remedy, as authorized by HCFA and/or the State Medicaid agency, to be effective no sooner than 15 days from receipt of this notice, but in no case later than 3 months from the date of the survey;

d. Provides requirements for an acceptable plan of correction within 10 calendar days and the fact that the plan of correction, as fully implemented, will serve as the facility's allegation of compliance. (See 1.f.);

e. Informs of the opportunity for informal dispute resolution;

f. Specifies that when an acceptable plan of correction is not submitted, the State may propose to the regional office and/or State Medicaid agency that remedies be imposed immediately within applicable notice requirements;

g. Informs the facility of the loss of Nurse Aide Training and Competency Evaluation Program and appeal rights if based on a finding of substandard quality of care, if applicable;

h. If substandard quality of care , refer to 1.k.; and

i. Provides the elements of an acceptable plan of correction. (See §7304.)

3. Initial Notice.--When immediate jeopardy exists, the surveying entity sends the initial notice to the provider of the following:

a. Nature of immediate jeopardy, including regulatory cites or initial assessment of immediate jeopardy findings;

b. Request for an allegation of removal of immediate jeopardy , including evidence of steps taken to remove the immediate jeopardy. The plan of correction will usually be deferred until immediate jeopardy has been determined to be removed;

c. Consequences of failure to submit an allegation of removal, e.g., provider agreement termination;

d. Remedies recommended with effective dates;

e. Opportunity for informal dispute resolution;

f. Loss of Nurse Aide Training and Competency Evaluation Program and appeal rights if based on a finding of substandard quality of care, if applicable; and

g. If substandard quality of care is determined, the facility must provide a list of physicians for residents identified with substandard quality of care on the survey. The State must notify each attending physician and refer the administrator to the State=s licensing board.

B. Regional Office, State Medicaid Agency, and State Formal Notices When Remedies are Imposed.--

1. Who Sends the Formal Notice of Remedies.--A formal notice of remedies is sent by:

a. The State, in its initial notice, for category 1 remedies and denial of payment for new admissions, as authorized by HCFA and/or the State Medicaid agency;

b. The regional office for remedies other than those provided in accordance with a. above; for skilled nursing facilities, skilled nursing facilities/nursing facilities, and nursing facilities where the regional office is taking the enforcement action; and/or

c. The State Medicaid agency for remedies other than those provided in accordance with a. above for nursing facilities.

2. Contents of the Formal Notice of Remedies.--The formal notice of remedies is notification to the provider of the following:

a. Facts regarding when the survey occurred, which requirements were found out of compliance, and, where applicable, subsequent actions on the part of the State or provider;

b. Basis for the enforcement remedy, including termination (i.e., the provider has failed to achieve substantial compliance);

c. Enforcement remedy(ies) being imposed and the effective date; e.g., no sooner than 2 days or 15 days from the facility's receipt of notice, depending on whether or not immediate jeopardy exists.

d. Appeal rights and how to request a formal appeal; and

e. The mandatory enforcement remedies not yet imposed that must occur at a later date if the provider continues to be out of compliance (i.e., mandatory denial of payment for new admissions and/or termination of the provider agreement).

3. Required Time Periods for Formal Notice.--The notice period begins once the provider receives its notice as indicated below.

a. Immediate Jeopardy.--

- State monitoring - no notice;
- Temporary management - 2 days;
- Termination - 2 days;
- Remedies, other than civil money penalties - 2 days; and
- Civil money penalties - effective either as of the date noncompliance began, which is usually the date of the survey, or as of the date of the "per instance" occurrence.

b. No Immediate Jeopardy.--

- State monitoring - no notice;
- Temporary Management - 15 days
- Termination - 15 days;
- Remedies, other than civil money penalties - 15 days; and
- Civil money penalties - effective either as of the date noncompliance began, which is usually the date of the survey, or as of the date of the "per instance" occurrence.

4. Nurse Aide Training and Compentency Evaluation Program/Competency Evaluation Program.--Instructions and notification requirements for the prohibition of or loss of a Nurse aide training and competency evaluation program or Competency evaluation program can be found in §4132.

C. Overlap of Notice of Remedies.--

1. When the State recommends a category 1 remedy and/or denial of payment for new admissions, and/or the regional office or State Medicaid agency imposes any other category of remedies at the same time, the regional office or State Medicaid agency will send the notice that includes both category 1 and/or denial of payment for new admissions, and other category remedies.

2. When the State recommends and provides notice, as authorized by the regional office or State Medicaid agency, of a category 1 remedy and/or denial of payment for new admissions, and the regional office or State Medicaid agency imposes other category remedies at a later date, both the State and the regional office or State Medicaid agency send separate notices.

D. Means of Sending Notice.--The notice shall be in writing and shall be addressed directly to the provider/facility; or to an individual, an officer, managing or general agent, or other agent authorized by appointment or law to receive the notice.

The notice shall be dispatched through first-class mail, or other reliable means. Other reliable means refers to the use of alternatives to the United States mail in sending notices. Electronic communication, such as facsimile transmission, is equally reliable and on occasion more convenient than the United States mail. If electronic means such as facsimile transmission are employed to send notice, the sender should maintain a record of the transmission to assure proof of transmission if receipt is denied.

7306. TIMING OF CIVIL MONEY PENALTIES

In the initial letter, the State notifies the facility when it will recommend that a civil money penalty be imposed for noncompliance, as described at §7510.

A. Civil Money Penalty Imposed Upon Finding of Noncompliance for a Facility With No Opportunity to Correct.--A facility is not given an opportunity to correct any deficiency against which a per instance civil money penalty was imposed. The State may recommend that a per day civil money penalty be imposed without an opportunity for the facility to correct deficiencies as a result of noncompliance found which constitutes immediate jeopardy or serious noncompliance (refer to §7304 for further guidance). In this case, the State notifies the regional office and/or State Medicaid agency of its recommendation (that the regional office or State Medicaid agency impose a civil money penalty) within 10 working days from the last day of the survey which determined non-compliance when immediate jeopardy does not exist, or 2 calendar days (one of which must be a working day) when immediate jeopardy exists. The regional office and/or State Medicaid agency responds quickly to the recommendation, and if accepted, sends out the formal notice in accordance with the notice requirements in §7305, and any additional requirements in §7520.

B. Per Day Civil Money Penalty Imposed Upon Failure to Correct.--When the State provides the facility with an opportunity to correct a revisit to occur later, but the State finds the provider is not in substantial compliance at the revisit, the State may recommend that a civil money penalty be imposed retroactive to the date the noncompliance began, which would usually be the last day of the survey.

C. When State Recommends a Civil Money Penalty for Past Noncompliance.--The State notifies the regional office and/or State Medicaid agency within 20 days from the last day of the survey which determined past non-compliance of its recommendation to impose a civil money penalty. The regional office and/or State Medicaid agency responds to the recommendation within 10 days, and if accepted, sends out the formal notice in accordance with the notice requirements in §7305 and §7520. (Past noncompliance is discussed in §7510.)

D. Amount.--Instructions for determining the amount of a civil money penalty can be found in §7516.

7307. IMMEDIATE JEOPARDY EXISTS

A. Statutory and Regulatory Basis.--Sections 1819(h)(2)(A)(I), 1919(h)(1)(A), and 1919(h)(3)(B)(1) of the Act, as well as 42 CFR 488.410, provide how cases involving immediate jeopardy will be processed. In addition, Appendix Q of the Interpretive Guidelines discusses immediate jeopardy.

B. Purpose.--Immediate action is required to remove the immediate jeopardy to resident health or safety (as defined in 42 CFR 488.301) and to subsequently correct the deficiencies. The application of the remedies of temporary management, termination, or both, is required to address immediate jeopardy situations. While the use of other remedies in addition to temporary management or termination is allowed, the Act makes it clear that the enforcement action for noncompliant facilities with immediate jeopardy deficiencies is intended to be swift.

7308. ENFORCEMENT ACTION WHEN IMMEDIATE JEOPARDY EXISTS

A. Action That **Must** Be Taken.--When the State identifies immediate jeopardy to resident health or safety, the State must notify the regional office, or the State Medicaid agency, or both, as appropriate, so that the regional office or State Medicaid agency either terminates the provider agreement within 23 calendar days of the last date of the survey, and/or appoints a temporary manager who must remove the immediate jeopardy within 23 calendar days of the last date of the survey. When the regional office imposes termination of a Medicaid provider agreement, it notifies the State Medicaid agency to terminate the agreement. However, action can be taken more quickly than 23 days as long as the required notice is given. In either case, the immediate jeopardy must be removed no later than 23 days from the last day of the survey or the provider agreement will be terminated.

When the regional office identifies immediate jeopardy to resident health or safety, the regional office must either take action itself, or notify the State Medicaid agency to take action to either terminate the provider agreement no later than 23 calendar days from the last date of the survey and/or appoint a temporary manager to remove the immediate jeopardy no later than 23 calendar days from the last date of the survey.

When immediate jeopardy is identified, the facility must submit an allegation that the immediate jeopardy has been removed. This allegation must include a plan of sufficient detail to demonstrate how and when the immediate jeopardy has been removed. In most cases, the plan of correction for the deficiencies will be deferred until a revisit to verify that the removal of the immediate jeopardy has been completed.

NOTE: In order for a 23-day termination to be stopped, the immediate jeopardy must be removed, even if the underlying deficiencies have not been fully corrected. Waiting for acceptable plans of correction can result in undue delay in determining removal of immediate jeopardy. Therefore, plan of corrections are usually deferred until the immediate jeopardy is removed.

If the facility alleges that the immediate jeopardy is removed and a revisit verifies that it has been removed but the facility is still not in substantial compliance, use the non-immediate jeopardy process, which requires a plan of correction for all citations.

B. Additional Action That **Must** Be Taken When Immediate Jeopardy to Resident Health or Safety Is Also Substandard Quality of Care.--Whenever a facility has deficiencies that constitute both immediate jeopardy to resident health or safety **and** substandard quality of care (as defined in 42 CFR 488.301), the survey agency must notify the attending physician of each resident found to have received substandard quality of care as well as the State board responsible for licensing the facility's administrator. Notify physicians and administrator licensing boards in accordance with §7320.

C. Enforcement Action That **Should** Be Taken.--The State will recommend to the regional office, or the State Medicaid agency, or both, as appropriate, that remedies, in addition to the required enforcement action(s) imposed in accordance with subsection A, be imposed against the noncompliant facility having deficiencies that constitute immediate jeopardy to resident health or safety. With the exception of civil money penalties in the lower range, the State may recommend imposition of additional remedies from any remedy category if it believes that such additional remedies will achieve and maintain compliance. If a civil money penalty is recommended for deficiencies that constitute immediate jeopardy, the State must choose either a per-day civil money penalty in the upper range (i.e., $3050 to $10,000 per day), or a per-instance civil money penalty between $1,000 and $10,000. This is in accordance with 42 CFR 488.438(a).

7309. KEY DATES WHEN IMMEDIATE JEOPARDY EXISTS

A. Second Calendar Day.--No later than 2 calendar days (one of which must be a working day) following the last day of survey which identified immediate jeopardy, the State notifies the skilled nursing facility or nursing facility in writing, by telegram, fax, or overnight express mail, that the State is recommending to the regional office (for skilled nursing facilities and skilled nursing facilities/nursing facilities) or to the State Medicaid agency (for nursing facilities) that the provider agreement be terminated. A temporary manager may be imposed in lieu of or in addition to termination. Any additional remedies may be imposed, if appropriate. This letter will serve as formal notice for imposition of any category 1 remedy or denial of payment for new admissions remedy, as authorized by HCFA and/or the State Medicaid agency. When this is the case, the letter should include the facility's right to informal dispute resolution and a formal appeal of the noncompliance which led to the category 1 remedy or denial of payment for new admissions remedy. Procedures pertaining to the imposition of temporary management can be found in §7550. The State also notifies the regional office and State Medicaid agency of its recommendation. (See §7305 for notice requirements.)

B. Fifth Calendar Day.--The State must forward all documentation (e.g., notice letter, contact reports, Form HCFA-1539, deficiencies, if completed) to the regional office or State Medicaid agency. The findings of immediate jeopardy will be included in the initial notice. These findings may be given in the form of an initial assessment of immediate jeopardy findings . The Form HCFA-2567 is not required to be sent out until the 10th working day following the last day of the survey.

C. Fifth to Twenty-First Calendar Day.--Except when formal notice of remedies is provided by the State, as authorized by HCFA and/or the State Medicaid agency, the regional office and/or the State Medicaid agency issues a formal notification of remedies to the facility (see §7305). In the case of an impending termination, notice is also given to the general public. In addition, the notice should include the facility's right to informal dispute resolution, and a formal appeal of the noncompliance which led to the temporary management remedy, termination, or any other enforcement actions (except State monitoring). For the temporary management remedy, the notice will advise the facility of the conditions of temporary management as specified in §7550, and that failure to relinquish control to the temporary manager will result in termination.

D. No Later Than 10th Working Day.--Copies of Form HCFA-2567 must be sent to the following: the facility, the regional office, and if the facility participates in Medicaid, the State Medicaid agency. The submission of an acceptable plan of correction is dependent upon whether the provider successfully removes the immediate jeopardy to stop the 23-day termination.

NOTE: The provider is not required to submit a plan of correction in order to get a revisit to verify the removal of the immediate jeopardy. It will submit an allegation of removal of the immediate jeopardy with sufficient information to show how the immediate jeopardy has been removed and the date of removal. In most cases, the plan of correction for Form HCFA-2567 will be deferred until the immediate jeopardy revisit has been conducted. If a plan of correction is to be submitted, it must be received no later than 10 calendar days after the provider receives the Form HCFA-2567.

E. By Twenty-Third Calendar Day.-- Termination takes effect unless the immediate jeopardy has been removed. If the immediate jeopardy has been removed, but substantial compliance has not been achieved, the skilled nursing facility or nursing facility may be given additional time (up to 6 months from the last day of survey) during which to achieve substantial compliance. (See §7316 for key dates when immediate jeopardy does not exist.)

7310. IMMEDIATE JEOPARDY DOES NOT EXIST

A. Introduction.--These procedures incorporate "1819(h)(2)(A)(ii), 1919(h)(1)(B), and 1919(h)(3)(B)(ii) of the Act, as well as implementing regulations in 42 CFR 488.412.

B. General.--The broad array of remedies vary in form and severity in recognition of the fact that there can be variations in impact posed by each violation of participation requirements. Therefore, while provider agreement terminations are authorized in non-immediate jeopardy cases, it is not generally necessary or desirable to choose that remedy when compliance may be achieved rapidly through imposition of one or more alternative remedies. Guidance for determining the scope and severity of identified deficiencies can be found in the regulations and in Appendix P. Guidance for selecting a remedy or remedies from those available may be found in 42 CFR 488.408 and in §7400.

7311. ENFORCEMENT ACTION WHEN IMMEDIATE JEOPARDY DOES NOT EXIST

A. Actions To Be Taken.--When the surveying entity finds that a facility's deficiencies do not pose immediate jeopardy to resident health or safety but the facility is not in substantial compliance (as defined in 42 CFR 488.301), the surveying entity may recommend that the enforcing entity either terminate the facility's provider agreement, or impose alternative remedies, (other than category 1 remedies or denial of payment for new admissions), or do both. The State may also provide formal notice of imposition of category 1 remedies and/or denial of payment for new admissions as authorized by HCFA and/or the State Medicaid agency. The facility must submit a plan of correction, as described in '7304. The action may be taken immediately or the facility may be given an opportunity to correct, as described in '7304.

B. Validation Authority.--When the regional office finds through a validation survey or review of the State's findings that any facility's deficiencies do not pose immediate jeopardy to resident health or safety but the facility is not in substantial compliance (as defined in 42 CFR 488.301), the regional office must, as appropriate, take action itself to terminate the facility's provider agreement (or stop Federal financial participation), or impose alternative remedies instead of terminating the provider agreement, or both; or direct the State Medicaid agency to terminate the facility's Medicaid provider agreement. HCFA=s authority to take enforcement action for any nursing facility, when HCFA finds the nursing facility to be out of compliance, is at §1919(h)(3)(A)+(B).

C. Additional Action That **Must** Be Taken When Substandard Quality of Care Is Identified.--Whenever a facility has deficiencies that constitute substandard quality of care (as defined in '7001), the State must notify the attending physician of each resident found to have received substandard quality of care as well as the State board responsible for licensing the facility's administrator. The procedures for notifying physicians and administrator licensing boards are discussed in §§7320 and 7906.

7312. CONSIDERATIONS AFFECTING ENFORCEMENT RECOMMENDATION TO IMPOSE REMEDIES WHEN IMMEDIATE JEOPARDY DOES NOT EXIST

If the State's recommendation is that alternative remedies be imposed **instead** of terminating the provider agreement, the criteria which permits a Medicare facility (for Medicare) and the State (for Medicaid) to receive continued Federal payment must be met. However, the provision requiring the State's agreement to repay for Medicaid was deleted by the Balanced Budget Act of 1997. The criteria are codified in 42 CFR 488.450 and are included in §7600. If any one of the criteria is not met, the recommendation to impose alternative remedies **instead** of termination cannot be made. When alternative remedies are not preferable as the sole enforcement response, the enforcing entity can either impose remedies in addition to terminating the provider agreement, or only terminate the provider agreement. However, at a minimum, the mandatory denial of payment for all new admissions remedy must be imposed and effective within 3 months from the last date of the survey if the facility has not achieved substantial compliance. (See 42 CFR 488.417 and '7506 for guidance about when and how to impose this mandatory remedy.)

The State recommends, (and/or as appropriate, imposes certain remedies as authorized by HCFA or the State Medicaid agency), termination, or termination plus alternative remedies, or alternative remedies instead of termination. (See §7600 for considering alternative remedies instead of termination.)

7313. PROCEDURES FOR RECOMMENDING ENFORCEMENT REMEDIES WHEN IMMEDIATE JEOPARDY DOES NOT EXIST

Once noncompliance is identified, the surveying entity decides whether to impose remedies immediately or give the facility an opportunity to correct. That decision is based on factors provided in '7304.

A. Facilities Subject to Immediate Remedies.--(See §7304.) The State recommends that remedies be imposed immediately. No later than 10 working days after the last day of the survey which identified the noncompliance, the State sends an initial notice (Exhibit 139) and the Form HCFA-2567. The notice provides that the State is recommending that remedies be imposed, provides when those remedies are likely to be effective and/or as appropriate, notifies the facility as authorized by HCFA and/or the State Medicaid agency of the imposition of category 1 remedies or denial of payment for new admissions, to become effective no sooner than 15 days from the date of this notice. The regional office and/or State Medicaid agency responds to the recommendation within 10 working days and sends out a formal notice to the provider imposing the remedy(ies.)

B. Facilities Given an Opportunity to Correct Before Remedies are Imposed.-- The State may provide an opportunity for the facility to correct its deficiencies and delay the imposition of remedies. The State requests a plan of correction and provides initial notice that failure to correct cited deficiencies will result in recommendation of remedies to HCFA or the State Medicaid agency, (and/or, as appropriate, provides a formal notice of imposition as category 1 remedies or denial of payment for new admissions, as authorized by HCFA and/or the State Medicaid agency, effective

no sooner than 15 days from the date of this notice). The State agency may, based on an acceptable plan of correction, presume a facility to be in substantial compliance as of a particular date specified in that plan of correction with a revisit conducted later to verify compliance. Or, based on an acceptable plan of correction, the State may conduct a revisit no sooner than the latest correction date specified in the approved plan of correction to determine if compliance has been achieved. The acceptance of a facility's plan of correction by itself, however, does not indicate a determination by either the State or HCFA that the facility has, in fact, corrected identified deficiencies. Only on-site verification can establish substantial compliance. If the facility is in substantial compliance at the revisit, no remedies will be imposed. If the facility has not achieved substantial compliance at the revisit, the State recommends that remedies be imposed and/or, that remedies be effective when notice of remedies has already been provided. If a civil money penalty is being recommended, the effective date of the civil money penalty is generally the last day of the original survey as described in §7518. The regional office and/or State Medicaid agency responds to the recommendation within 10 working days and sends out the formal notice to the provider imposing the remedy(ies). (See §7305 for notice requirements.)

When the State determines noncompliance at the revisit, it will recommend remedies proposed. The State notifies the regional office and the State Medicaid agency of its recommendation of choice of remedy and the timing for imposing such remedies. .

The regional office and State Medicaid agency establish procedures with the State as to when and how the documentation of noncompliance is to be communicated.

7314. SPECIAL PROCEDURES FOR RECOMMENDING AND PROVIDING NOTICE OF CATEGORY 1 REMEDIES AND DENIAL OF PAYMENT FOR NEW ADMISSIONS

When the State provides formal notice of the imposition of a category 1 remedy and/or denial of payment for new admissions, as delegated by HCFA and/or the State Medicaid agency, the State notifies the regional office and the State Medicaid agency of its proposed imposition of directed in-service training, a directed plan of correction and/or State monitoring when applicable.

The notice to the regional office or State Medicaid agency can be electronic or written. If the regional office or State Medicaid agency has not indicated its disapproval of the category 1 remedies and/or denial of payment for new admissions within 2 calendar days (at least one of which is a work day) of the date of notice, the State sends a letter to the facility stating that Aas authorized by HCFA and/or the State Medicaid agency, (as appropriate) a category 1 remedy and/or denial of payment for new admissions is being imposed (see '7311 for HCFA=s authority to take enforcement action against any nursing facility). A State official signs the letter on behalf of the regional office and State Medicaid agency. A copy of the letter is sent to the regional office and State Medicaid agency.

7315. DISAGREEMENTS ABOUT REMEDIES WHEN IMMEDIATE JEOPARDY DOES NOT EXIST

Disagreements between the regional office and the State Medicaid agency regarding the application of remedies, including the remedy of termination and its timing, should be resolved in accordance with 42 CFR 488.452 and '7807. If the regional office disagrees with the State's recommendation, the regional office will contact the State Medicaid agency and the State to resolve the differences.

7316. KEY DATES WHEN IMMEDIATE JEOPARDY DOES NOT EXIST

A. Required Actions When There Is An Opportunity to Correct.--

1. By no later than the 10th working day after the last day of the survey, the State must forward to the provider Form HCFA-2567, and an initial letter and other documents and information in accordance with §7305.A.1. This letter may also provide official notice for imposition of category 1 remedies and/or denial of payment for new admissions by the State, as authorized by HCFA and/or the State Medicaid agency (see §7305).

2. By the 10th calendar day after the facility receives Form HCFA-2567, it submits its plan of correction to the State addressing the required elements as described in §7304.

3. If the provider does not submit an acceptable plan of correction by the 10th calendar day after it receives the Form HCFA-2567, the State notifies the facility that it is recommending to the regional office and/or the State Medicaid agency that remedies be imposed effective as soon as notice requirements are met and/or to effectuate category 1 remedies and/or denial of payment for new admissions. (Civil money penalties may be imposed retroactively, predating the initial notice.)

4. If the State finds the plan of correction acceptable, it notifies the facility by phone, e-mail, etc. The State sends written notice to the provider if the plan of correction is unacceptable. The letter also states recommended remedies if substantial compliance is not verified during a revisit. (See §7305 for notice requirements.)

5. Except in the case of category 1 remedies and denial of payment for new admissions, if applicable, the regional office and State Medicaid agency **must** provide notice, before enforcement actions are imposed and effective in accordance with §7305.

6. The regional office and/or State Medicaid agency may provide notice for category 1 remedies and/or denial of payment for new admissions.

7. The State may provide notice as authorized by the regional office and/or State Medicaid agency of category 1 remedies and/or denial of payment for new admissions, if applicable.

8. No later than the 3rd month after the last day of the survey, the regional office and/or State Medicaid agency must impose a mandatory denial of payment for all new admissions. (See §7506.) Official notice of this remedy may have already been provided in the State's initial letter to the provider (see §7305).

9. No later than the 6th month after the last day of the survey, termination is effective, or if an agreement to repay is signed for Medicare, Federal funding is stopped.

10. The facility may request informal dispute resolution during the same 10 calendar days it has for submitting its plan of correction to the surveying entity; and

11. If the State chooses to impose a category 1 remedy and/or denial of payment for new admissions, if applicable, it notifies the regional office and/or the State Medicaid agency 2 calendar days (at least one of which is a working day) before notice is sent to the facility.

B. Required Actions When There is No Opportunity to Correct.--

1. By no later than 10 working days after the last day of the survey, the State must forward to the provider Form HCFA-2567, an initial letter, and other documents and information in accordance with '7305A.2. This letter may also provide official notice for imposition of category 1 remedies and/or denial of payment for new admissions, by the State, as authorized by HCFA and/or the State Medicaid agency. (See '7305.)

2. Within the same 10 working days, and when the State is not imposing any remedies, as authorized by HCFA and/or the State Medicaid agency, the State forwards notice to the regional office and/or State Medicaid agency of its recommendation(s) for immediate remedies.

3. The regional office or State Medicaid agency must provide formal notice ('7305) of the remedies imposed unless official notice has already been provided by the State, as authorized by HCFA and/or the State Medicaid agency.

4. By the 10th calendar day after the facility receives Form HCFA-2567, it submits its plan of correction to the State addressing the core elements as described in '7304.

5. The State may provide notice, as authorized by the regional office or State Medicaid agency, of imposition of category 1 remedies and/or denial of payment for new admissions.

6. No later than the 3rd month after the last day of the survey, the regional office or State Medicaid agency must impose the mandatory denial of payment for new admissions. (See '7306.)

7. No later than the 6th month after the last day of the survey, termination is effective and Federal funding is stopped.

8. A revisit must be conducted to determine compliance and stop any remedy imposed.

9. The provider may request informal dispute resolution during the same 10 calendar days it has for submitting the plan of correction to the surveying entity.

10. If the State chooses to impose a category 1 remedy and/or denial of payment for new admissions, if applicable, it notifies the regional office and/or the State Medicaid agency 2 calendar days (at least one of which is a working day) before notice is sent to the facility.

7317. RESPONSE TO THE PLAN OF CORRECTION

A. The plan of correction serves as the facility=s allegation of compliance in non-immediate jeopardy cases. The State can respond to the allegation of compliance in a number of ways.

1. Conduct Revisit.--If the State determines that the plan of correction is acceptable, it will conduct a revisit near the time that the provider alleges all corrections have been made, but it will not be conducted prior to the latest date of correction. Surveyors should focus on what has occurred since correction dates; a determination of noncompliance is not based on problems which took place during the correction period. While facilities are expected to correct deficiencies at levels B and C, deficiencies at this level are within the substantial compliance range and, therefore, need not be reviewed for correction during subsequent revisits within the same survey cycle.

The State conducts a revisit any time between the last correction date on the plan of correction and the 60th day from the survey date to confirm that the facility is in substantial compliance and, in certain cases, has the ability to remain in substantial compliance. Conducting a revisit before the 60th day allows time for notice of a mandatory denial of payment for all new admissions at the 90th day, if necessary. If the facility is found in substantial compliance, the State will grant a certification of compliance.

If the State finds that the facility is not in substantial compliance at the time of the revisit, the State:

- o Recommends to the regional office and/or State Medicaid agency that the enforcement remedy(ies) originally proposed in the initial letter be imposed;

- o Recommends revised remedies be imposed as a result of changes in the seriousness of the noncompliance; and

- o Effectuates any category 1 remedy and/or denial of payment for new admissions for which formal notice was provided in the initial notice (as authorized by HCFA and/or the State Medicaid agency).

To illustrate the former, if the initial letter provided formal notice that denial of payment for new admissions would be imposed if the facility was not in substantial compliance by the 30th day, and if on the 60th day the revisit finds noncompliance, denial of payment for new admissions would be imposed immediately, but no sooner than 15 days from the date the facility received notice of its imposition. If the remedy is a per day civil money penalty, it would be effective from the date of the noncompliance which is usually the last day of the survey which first found the noncompliance. Regarding the imposition of civil money penalties when the revisit finds that the seriousness of the noncompliance has changed, consider the following: If the seriousness of the noncompliance has lessened, imposition of a civil money penalty may no longer be appropriate; if the noncompliance has worsened, but is not immediate jeopardy, a civil money penalty in a higher amount than originally specified, but within the range for non-immediate jeopardy, may be appropriate.

2. Accept Written Documentation That Facility is in Substantial Compliance in Lieu of Revisit.--Except as provided in 3. below, an onsite revisit may not be necessary to determine if the facility is in substantial compliance with the requirements. If a remedy has already been imposed, the remedy remains in effect until the date of the documentation confirming substantial compliance has been achieved, and, if required by the regulations, documentation confirming that compliance will be maintained. If a remedy has not been imposed, the State will not recommend imposition of a remedy based on the evidence of substantial compliance.

3. If a facility is surveyed and deficiencies are found to constitute substandard quality of care, or are at level G or above, the discretion to waive an onsite revisit will not apply to the facility now **or** at a later date within the same survey cycle. When this occurs, onsite revisits must verify that a facility has achieved substantial compliance with all requirements. (See B. below which requires prior regional office approval when more than 2 revisits are requested.)

B. A facility is not entitled to any revisits; they are done at the discretion of HCFA or the State. However, a revisit will normally be done following a survey which found noncompliance and another before the expiration of the 6-month period by which a facility must be in substantial compliance to avoid termination of its provider agreement. If a facility requests more than two revisits, authorization must be obtained from the regional office.

7318. NEW DEFICIENCIES IDENTIFIED

A. New Deficiencies Found During Revisit and Original Deficiencies Not Corrected.--When a facility has deficiencies cited at the original survey, does not correct one or more of these deficiencies at the revisit, and new deficiencies are also determined at revisit, the remedies recommended when the plan of correction was accepted or those for which formal notice has already been provided, will be imposed. The provider may dispute penalties all deficiencies from the revisit through the informal dispute resolution process. (See §7212.) If new deficiencies constitute immediate jeopardy, action is taken in accordance with§7308.

B. New Deficiencies Found During Revisit and Original Deficiencies Are Corrected.--When a facility has deficiencies cited at the original survey, corrects those deficiencies (as verified at the revisit) but has new deficiencies that constitute noncompliance at revisit, the regional office and State Medicaid agency, or State, as appropriate, are obligated to give providers a 15-day notice before imposing remedies, except civil money penalties and State monitoring. This action is taken because no period of compliance has been determined. However, if substantial compliance is not achieved, the regional office and State Medicaid agency have the discretion to allow correction of subsequent deficiencies before remedies will be imposed. In any case, the provider must be in substantial compliance by the 3rd month after the last day of the original survey or denial of payment for new admissions must be imposed.

C. New Deficiencies Found After Facility Has Been Certified in Compliance.--When a provider has been certified as being in substantial compliance and deficiencies are subsequently identified, those deficiencies begin a new enforcement time frame. A mandatory denial of payment remedy must be imposed and effective no later than the end of the 3rd month following the survey which identified the new deficiencies.

7319. PROCEDURES FOR CERTIFYING COMPLIANCE

A. Non-State Operated Skilled Nursing Facilities and Nursing Facilities or Skilled Nursing Facilities/Nursing Facilities.--

1. The State conducts the survey and certifies compliance.

2. The State sends the facility a copy of Form HCFA-2567 and/or the "Notice of Isolated Deficiencies Which Cause No Actual Harm With the Potential for Minimal Harm" (Form A), if applicable, within 10 working days of the last day of survey.

3. If the facility is in substantial compliance, but deficiencies constitute a pattern or widespread findings causing no actual harm and potential for only minimal harm, the State instructs the facility to submit a plan of correction to the State's office. (This must be submitted within 10 calendar days after the facility has received its statement of deficiencies.) There is no requirement for the State to conduct a revisit to verify correction, but the facility is expected to comply with its plan of correction.

4. If the facility is in substantial compliance, but deficiencies are isolated with no actual harm and potential for only minimal harm, the State records the deficiencies on Form A. A plan of correction is not required, but providers are expected to correct these deficiencies.

5. The State enters the certification information on the Certification and Transmittal Form (Form HCFA-1539) into the Online Survey, Certification and Reporting System. This can occur as soon as substantial compliance is achieved.

B. State-Operated Facilities.--

1. The State conducts the survey and documents its findings on Form HCFA-2567 and/or on Form A.

2. The State forwards its survey findings to the regional office within 10 days of the last day of the survey.

3. If the facility has deficiencies that are widespread or constitute a pattern and which cause no actual harm and potential for only minimal harm, the regional office instructs the facility to submit its plan of correction to the regional office. The plan of correction must be submitted within 10 calendar days after the facility has received its statement of deficiencies.

4. The regional office enters the certification information on the Certification and Transmittal Form (Form HCFA-1539) into the Online Survey, Certification and Reporting System.

7320. ACTION WHEN THERE IS SUBSTANDARD QUALITY OF CARE

Sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Act and 42 CFR 488.325 require that when a facility is found to have provided substandard quality of care, notification of that finding must be provided to the attending physician of each resident found to have received such care as well as to the State board responsible for licensing the facility's administrator. The facility's ability to provide a nurse aide training and competency evaluation program must also be prohibited for 2 years from the date of the finding of substandard quality of care.

A. Repeated Substandard Quality of Care.--

1. Action To Be Taken When Facility Is Found To Have Provided Substandard Quality of Care on Last Three Standard Surveys.--Sections 1819(h)(2)(E) and 1919(h)(2)(D) of the Act and 42 CFR 488.414 require that when a facility has been found to have provided substandard quality of care (as defined in 42 CFR 488.301) on the last three consecutive standard surveys, HCFA or the State Medicaid agency, as appropriate, must, regardless of other remedies:

- Deny payment for all new admissions no later than 3 months from the last day of the third consecutive survey in accordance with §7506;
- Impose State monitoring in accordance with §7504; and
- Provide notification of the finding of substandard quality of care to the attending physician of each resident found to have received such care, as well as to the State board responsible for licensing the facility's administrator. These notifications occur whenever there is a finding of substandard quality of care.

2. Factors Which May or May Not Affect A Determination of Repeated Substandard Quality of Care.--The fact that a facility has had any change in its program participation will not affect this determination. In other words, any standard survey completed for Medicare, Medicaid, or both, will be considered in this determination. Termination of a facility would allow the count of repeated substandard quality of care surveys to start over. A change of facility ownership would not allow the count to start over unless the new owner can demonstrate to the State's satisfaction that the poor past performance is no longer a factor due to the change of ownership.

3. Notification Requirements.--Notification to the facility by HCFA, or the State Medicaid agency, or the State, as appropriate, would be in accordance with 42 CFR 488.402. The notice will inform the facility that the remedies will continue until the facility has demonstrated that it is in substantial compliance with the requirements and that it will remain in substantial compliance with the requirements. The facility will also be notified that it cannot avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it either alleges correction of the deficiencies cited in the most recent standard survey, or when it achieves compliance before the effective date of the remedies. The finding of repeated substandard quality of care results in the imposition of the remedies specified in subsection 1., regardless of subsequent correction.

7321. SKILLED NURSING FACILITY OR SKILLED NURSING FACILITY/NURSING FACILITY READMISSION TO MEDICARE OR MEDICAID PROGRAM AFTER TERMINATION

A. Readmission Criteria.--The general guidelines for readmission can be found in '2016.

B. Reasonable Assurance Concept.--A Medicare provider terminated under 42 CFR 489.53 may not be reinstated into the Medicare program until it has been verified through the "reasonable assurance" process that the provider is capable of achieving and maintaining substantial compliance with all applicable participation requirements. There is no statutory or regulatory requirement that States must establish a reasonable assurance period for facilities seeking readmission as a Medicaid-only facility. However, if a terminated facility is readmitted as a nursing facility, without undergoing a reasonable assurance period, before it can reenter the Medicare program as a skilled nursing facility or skilled nursing facility/nursing facility, it must successfully undergo the Medicare reasonable assurance process. This means that the facility must be found in substantial compliance during one survey at the beginning, and another survey at the end, of the reasonable assurance period, before the facility will be readmitted into the Medicare program. The regional office (at its discretion) may accept the Medicaid re-entry survey as the initial reasonable assurance survey. If the facility is found not to be in substantial compliance during either reasonable assurance survey, then the facility's application for readmission to the Medicare program following termination is denied, and the facility's Medicaid provider agreement is subject to termination.

The reasonable assurance decision is an administrative action (not an initial determination) and is not subject to the appeals process at 42 CFR 498.3(d)(5).

C. Reasonable Assurance Surveys.--Two surveys are required to verify that the reason for termination no longer exists and that the provider has maintained continued compliance. While both visits need not be full surveys, the regional office may require, at its discretion, two full surveys be done in any particular case. Typically, if both visits are not full surveys, the first one is partial and the second full. The first survey is conducted at the beginning of the reasonable assurance period to document compliance with the requirements for which there were previous deficiencies. The second is a full/standard survey at the end of the reasonable assurance period to document compliance with participation requirements.

1. First Visit.--The first visit only needs to determine whether the deficiencies which led to the termination have been corrected (i.e., are they now completely removed or at the level of substantial compliance). If, upon looking into compliance in these problematic areas, the State's first visit finds:

a. When there are deficiencies or only a deficiency(ies) at levels A, B, or C, the facility is in substantial compliance. Therefore, the first visit is acceptable as the first of two mandatory surveys. Any deficiencies found in boxes B and C during the first visit continue to require the submission of a plan of correction. This visit may be the survey conducted for Medicaid recertification following termination. If a second survey, conducted at the end of the reasonable assurance period, finds that the facility has maintained substantial compliance throughout that period, the facility may qualify for readmission to the Medicare program.

The regional office then sets the reasonable assurance period, after which a second (full) survey will be completed. Sometimes, the reasonable assurance period will have already been set by the regional office in the termination notice. The reasonable assurance period can vary from 1 month to 6 months based upon the regional office's judgment of the period necessary to ensure that the facility demonstrates its ability to maintain compliance.

b. A deficiency(ies) that falls at level D or higher on the first visit will result in a denial for starting Medicare reasonable assurance. The facility does not need to submit a plan of correction.

c. Any subsequent visit which finds substantial compliance may start the reasonable assurance period.

d. Following certification for Medicaid, and prior to certification for Medicare, any visit which determines noncompliance (either based on a complaint or incident) will result in a finding that reasonable assurance has not been demonstrated. The regional office will issue a denial notice and start the period of reasonable assurance again when the State determines that substantial compliance has been achieved.

2. Second Visit.--The second visit will typically be a full survey.

EXCEPTION: The regional office may instruct the State to conduct the full survey during the first visit and the partial survey at the second.

a. If the survey finds no deficiencies or only a deficiency(ies) that falls at levels A, B, or C, the facility is in substantial compliance, and the survey is acceptable for program participation purposes. The facility must submit a plan of correction for any level B and/or C deficiencies found during the second visit/full survey.

b. If the survey finds deficiencies or only a deficiency that falls at levels D, E, or F AND that deficiency is in the same regulatory grouping as the deficiency(ies) that caused the facility=s termination, the survey is unacceptable. The regional office will issue a notice of denial of participation.

c. If the survey finds a deficiency(ies) that falls at levels D, E, or F, and the survey finds substandard quality of care, the survey is unacceptable. The regional office will issue a notice of denial of participation.

d. If the survey finds a deficiency(ies) that falls at levels D, E, or F that does not constitute substandard quality of care and is not in the same regulatory grouping as the deficiencies which caused termination, the regional office MAY accept the second visit/full survey for participation based upon receipt of an acceptable plan of correction for all deficiencies above level A, and verification of substantial compliance via an onsite visit.

e. If the survey finds a deficiency(ies) above level F (which would constitute actual harm), the survey is not acceptable for participation. The regional office will issue a notice of denial of participation.

D. Effective Date of Provider Agreement.--The controlling regulation for setting the effective date of the provider agreement is 42 CFR 489.13(b)(3), which provides that the agreement is effective on the date the skilled nursing facility is in substantial compliance as defined in 42 CFR 488.301 (and submits an approvable waiver request, if applicable). 42 CFR 488.301 defines substantial compliance as having no deficiencies above level C with an acceptable plan of correction. This is paralleled at 42 CFR 488.330(f). The effective date is the date the second visit/full survey (or its followup visit, where required as indicated below) finds substantial compliance.

1. If the second visit finds substantial compliance, the effective date is the survey completion date, regardless of whether the visit is a full or a partial survey.

2. If, on the second visit, HCFA accepted a plan of correction for deficiencies at levels D, E, or F, the effective date is the date of the facility's attainment of substantial compliance, as verified by a single onsite followup visit conducted by the State. This can be a date during the followup visit or an earlier date that the State can verify.

NOTE: The new provider agreement is signed and issued only after the facility has provided an acceptable plan of correction for any deficiencies that fall at levels B and/or C. While the plan of correction submittal date does not determine the effective date of the agreement, the facility must meet this requirement before an agreement can be issued per 42 CFR 488.402(d). This regulation requires that the facility must provide an acceptable plan of correction for any deficiencies above level A.

REASONABLE ASSURANCE EXAMPLES

The following examples are illustrative only and do not purport to control any specific case. Terminations occur for a variety of reasons, and the regional office and State will need to exercise discretion in each case.

EXAMPLE 1: NURSING HOME A.

Prior History. Nursing Home A is a 150-bed skilled nursing facility/nursing facility located in a rural area. The facility serves residents with a high acuity level. It is part of a large national, for-profit chain. The facility had been in the program since 05/01/78. Surveys had revealed condition-level noncompliance in 1987, 1988, 1989, and five level A deficiencies in 1994. The facility avoided termination each time by correcting its deficiencies prior to termination. The facility underwent a change of ownership on 6/1/96. Since 07/01/95, the facility had been out of compliance in 1996, 1997, and 1998 surveys, but avoided enforcement remedies by attaining compliance by "date certain" The highest level of noncompliance had been at level G during this time with no substandard quality of care. Thus, between the change of ownership in 1996 and the current cycle of surveys leading to termination, the facility's compliance history had been fair.

The termination. The facility was terminated from both programs on 08/08/99 for failure to attain substantial compliance with program requirements as demonstrated on five State visits within a 6-month period. The survey cycle started with a 02/08/99 complaint investigation which revealed 22 deficiencies, with no actual harm, and the highest scope and severity of one level F (substandard Quality of Care due to poor record-keeping of criminal background checks). After an opportunity to correct, a revisit and another complaint investigation conducted on 04/12/99 revealed continued noncompliance, again with 22 deficiencies, many of which were the same deficiencies (again no harm). A second revisit on 06/16/99 revealed continued noncompliance with 10 deficiencies, two of which were at level G. The third revisit on 07/26/99 was also a standard survey, which revealed 28 deficiencies, with no harm and no substandard quality of care. At this point the organization infused the facility with many additional resources and a decision was made to revisit a final time. The final revisit was conducted on 08/10/99 and found only 3 deficiencies at the noncompliance level (two level D's and one level E). Termination was effective 08/08/99 since the facility was not in substantial compliance within 6 months.

Reasonable Assurance Decision. The facility first applied for Medicaid-only recertification. Medicare certification was not initially sought due to the delay in Form HCFA-855 review by the fiscal Intermediary, the prohibition on the conduct of a Medicare survey pending Form HCFA-855 clearance, and the absence of a reasonable assurance requirement for re-entry into the Medicaid program. Since this would be the initial certification survey for Medicaid, the tasks of both the standard and extended surveys are required, as well as confirming compliance with all regulatory requirements. The Medicaid re-entry survey was conducted on 09/11/99, with only two level B deficiencies. The facility was certified for Medicaid effective 09/11/99, the date of receipt of an acceptable plan of correction. On 09/12/99, the facility applied for re-entry into the Medicare program. After Form HCFA-855 clearance by the fiscal intermediary on 11/15/99, the regional office determined that, based on the initial Medicaid survey, the cause for termination had been removed. The regional office established a reasonable assurance period of 90 days from the date of the Medicaid survey on 09/11/99. Thus, the second reasonable assurance survey, a standard survey, would be conducted after 12/11/99.

Rationale. A 90-day reasonable assurance period was chosen due to the fact that the facility remained out of compliance, having many of the same deficiencies over a 6-month period. A longer period was not deemed necessary in consideration of the following: (1) The "clean" Medicaid re-entry survey, even though residents continued with a high acuity level; (2) A fair history of compliance since the change of ownership; (3) The State was late in conducting the "annual survey" until 2 weeks before the termination date, yet the facility removed all but three deficiencies by the termination date; (4) The lack of actual harm on 3 of 5 visits, with only three deficiencies at a level G over the entire 6-month period despite the fact that the facility provided services to residents with a very high acuity level; and (5) The lack of additional, satisfactory Medicare beds in the area, with the closest facility with vacancies determined to be a problem chain facility in bankruptcy.

EXAMPLE 2: NURSING HOME B.

Prior History. Nursing Home B is a 100-bed skilled nursing facility/nursing facility located in a major metropolitan area. It has been in both programs since 1968. It was previously owned and operated by a large national chain until 1992, when the facility was leased by a local corporation which operates no other nursing homes. In 1989, the facility had two Conditions of Participation not met. In 1990, one Level A deficiency (refers to participation requirement level designation prior to7/1/95) was cited. From 1991-1994, several Level B deficiencies (refers to participation requirement level designation prior to 7/1/95 were cited on each survey, but no Level A findings. From 07/01/95 through 03/20/98, the facility had no findings of substandard quality of care, with one level G, actual harm cited 03/20/98. In 1995, the remedy of denial of payment for new admissions was initiated, but rescinded as the facility attained compliance prior to the effective date of the remedy. Prior to the 1999 survey cycle, no enforcement actions had ever been taken since the facility consistently corrected its deficiencies after an opportunity to correct.

The termination. The facility was terminated from both programs effective 07/19/99 due to continued noncompliance cited on five surveys/follow-ups over a 6-month period. The cycle started with a 01/19/99 complaint survey which revealed 13 deficiencies, 3 of which were actual harm in Quality of Care. After an opportunity to correct, the State returned on 03/19/99 and conducted a follow-up and a standard/extended survey which revealed 23 deficiencies, with 2 deficiencies reflecting substandard quality of care. Another revisit on 5/19/99 revealed 19 deficiencies, with an immediate jeopardy. A 5/21/99 monitoring revisit documented abatement of the immediate jeopardy, but the prior deficiencies remained. The facility alleged compliance again and the State conducted the final revisit on 07/09/99, with 8 cited deficiencies including actual harm and one substandard quality of care. Upon receipt of the regional office's termination notice, a chain organization (with no other facilities in the State), alleged to have purchased the facility on 3/1/99

and asked the regional office to stop all remedies based on the change of ownership. The regional office did not authorize an additional revisit beyond the 07/09/99 follow-up since, in spite of the facility's repeated allegations of compliance, subsequent revisits found worsening noncompliance. In addition, no change of ownership application had been submitted. Termination was effective on 07/19/99.

Reasonable Assurance Decision. The facility applied for recertification as a Medicaid-only facility in order to facilitate re-entry and avoid the delays of the fiscal intermediary's Form HCFA-855 review. The Medicaid survey was conducted on 08/20/99 and revealed noncompliance with actual harm with a requirement which was the basis for termination. The facility alleged compliance, a revisit was conducted on 09/10/99, which revealed compliance. Medicaid certification was effective 09/10/99. Since re-entry into the Medicaid program on 09/10/99, the State returned to the facility on 12/1/99 to investigate complaints and found noncompliance in one of the regulations which led to the previous termination. The State gave the facility an opportunity to correct before imposing remedies. The facility alleged compliance and a revisit was conducted on 01/19/2000 which found substantial compliance.

The facility applied for Medicare recertification on 03/01/2000. Upon clearance from the fiscal intermediaries of Form HCFA-855 on 05/05/2000, the regional office established a reasonable assurance period of 150 days, with two Medicare re-entry surveys required. The Medicaid surveys were not accepted by the regional office as a part of its reasonable assurance determination. As a result, the 150-day reasonable assurance period begins with a State survey to determine if the cause for termination still exists. The first reasonable assurance survey was conducted on 05/29/2000. Two level D deficiencies were cited, with neither being the cause for termination. That survey was accepted by the regional office for establishing the 150-day reasonable assurance period on 05/29/2000. Thus, the State will return after 10/29/2000 to conduct the second reasonable assurance survey (standard and extended survey tasks, as well as confirm compliance with all regulatory requirements).

Rationale. A 150-day reasonable assurance period was sought because: (1) The facility had a worsening compliance record during the 6 months leading to termination; (2) Upon re-entry into Medicaid following termination, the facility could not maintain compliance; and (3) The change of ownership was considered in determining the length of the reasonable assurance process, but was overshadowed by the facilitys failure to maintain compliance following termination.

Enforcement Process

7400. ENFORCEMENT REMEDIES FOR SKILLED NURISNG FACILITIES AND NURSING FACILITIES

A. Introduction.--Sections 1819(h) and 1919(h) of the Act, as well as 42 CFR 488.404, 488.406, and 488.408, provide that HCFA or the State may impose one or more remedies in addition to, or instead of, termination of the provider agreement when the State or HCFA finds that a facility is out of compliance with participation requirements. The remedies available to the regional office, the State Medicaid agency, or both, as appropriate, are listed in subsection C.

B. General.--The nursing home enforcement protocol/procedures are based on the premise that all requirements must be met and enforced, and requirements take on greater or lesser significance depending on the specific circumstances and resident outcomes in each facility.

A skilled nursing facility, nursing facility, or dually participating facility (skilled nursing facility/nursing facility) will be subject to one or more enforcement remedies for noncompliance with one or more participation requirements. Each facility that has deficiencies (other than those isolated deficiencies that have been determined to constitute no actual harm with potential for only minimal harm) must submit an acceptable plan of correction. HCFA's requirement relative to submittal of plans of correction can be found in '7304. A plan of correction is not an enforcement remedy.

It is important to note that '1919(h)(3)(A)&(B) provides HCFA with authority to take enforcement action against any nursing facility when it finds that the nursing facility is no longer in compliance with participation requirements.

C. Listing of Remedies.--

1. Available Enforcement Remedies.--In accordance with 42 CFR 488.406, the following remedies are available:

- Termination of the provider agreement;
- Temporary management;
- Denial of payment for all Medicare and/or Medicaid residents by HCFA;
- Denial of payment for all new Medicare and/or Medicaid admissions;
- Civil money penalties;
- State monitoring;
- Transfer of residents;
- Transfer of residents with closure of facility;
- Directed plan of correction;
- Directed in-service training; and
- Alternative or additional State remedies approved by HCFA.

2. Mandatory Enforcement Remedies.--Regardless of what other remedies the State Medicaid agency may want to establish in addition to the remedy of termination of the provider agreement, it must establish, at a minimum, these statutorily specified remedies or an approved alternative to these specified remedies:

- o Temporary management;
- o Denial of payment for all new admissions;
- o Civil money penalties;
- o Transfer of residents;
- o Transfer of residents with closure of facility; and
- o State monitoring.

The State Medicaid agency may establish additional or alternative remedies provided that the State has been authorized by HCFA to do so under its State plan. Guidance on the review and approval (or disapproval) of State Plan amendment requests for alternative or additional remedies can be found in '7805.

3. Availability of State Medicaid Agency Remedies to the Regional Office in Dually Participating Facilities.--Whenever a State Medicaid Agency's remedy is unique to its State plan and has been approved by HCFA, then that remedy may also be imposed by the regional office against the Medicare provider agreement of a dually participating facility in that State. For example, where HCFA has approved a State's ban on admissions remedy as an alternative remedy under the State plan, HCFA may impose this remedy but only against Medicare and Medicaid residents; only the State can ban the admission of private pay residents.

D. Measuring Seriousness of Deficiencies.--Measuring the seriousness of deficiencies is only for the purpose of determining the enforcement response most appropriate for specific degrees of noncompliance. The system by which the seriousness of deficiencies is rated (i.e., harm and scope factors), is a national system to be used by States and HCFA. Immediate jeopardy has historically been determined by guidance provided in Appendix Q of the Interpretive Guidelines and will continue to be determined using that guidance. Appendix P of the Interpretive Guidelines provides guidance on how to determine the seriousness of non-immediate jeopardy deficiencies.

E. Selection of Remedies.--

1. Factors That Must Be Considered When Selecting Remedies.--In order to select the appropriate remedy(ies) for a facility's noncompliance, the seriousness of the deficiency(ies) must first be assessed, because specific levels of seriousness correlate with specific categories of enforcement responses. The assessment factors that must be used to determine the seriousness of deficiencies are presented on the visual matrix which follows later in this subsection. These factors are also listed below. They relate to whether the deficiencies constitute:

- o No actual harm with a potential for minimal harm;
- o No actual harm with a potential for more than minimal harm but not immediate jeopardy;

- Actual harm that is not immediate jeopardy; or,
- Immediate jeopardy to resident health or safety.

AND, whether deficiencies:

- Are isolated;
- Constitute a pattern; or,
- Are widespread.

	Isolated	Pattern	Widespread
Immediate jeopardy to resident health or safety	J PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	K PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	L PoC Required: Cat. 3 Optional: Cat. 2 Optional: Cat. 1
Actual harm that is not immediate jeopardy	G PoC Required* Cat. 2 Optional: Cat. 1	H PoC Required* Cat. 2 Optional: Cat. 1	I PoC Required* Cat. 2 Optional: Cat. 1 Optional: Temporary Mgmt.
No actual harm with potential for more than minimal harm that is not immediate jeopardy	D PoC Required* Cat. 1 Optional: Cat. 2	E PoC Required* Cat. 1 Optional: Cat. 2	F PoC Required* Cat. 2 Optional: Cat. 1
No actual harm with potential for minimal harm	A No PoC No Remedies Commitment to Correct Not on HCFA-2567	B PoC	C PoC

Substandard quality of care is any deficiency in 42 CFR 483.13, Resident Behavior and Facility Practices, 42 CFR 483.15 Quality of Life, or 42 CFR 483.25, Quality of Care, that constitutes immediate jeopardy to resident health or safety; or, a pattern of or widespread actual harm that is not immediate jeopardy; or, a widespread potential for more than minimal harm that is not immediate jeopardy, with no actual harm.

Substantial compliance

REMEDY CATEGORIES

Category 1 (Cat.1)	Category 2 (Cat.2)	Category 3 (Cat.3)
Directed Plan of Correction State Monitor; and/or Directed In-Service Training	Denial of Payment for New Admissions Denial of Payment for All Individuals imposed by HCFA; and/or Civil money penalties: $50 - $3,000/day $1,000 - $10,000/instance	Temp. Mgmt. Termination Optional: Civil money penalties 3,050-$10,000/day $1,000 - $10,000/instance

Denial of payment for new admissions must be imposed when a facility is not in substantial compliance within 3 months after being found out of compliance.
Denial of payment and State monitoring must be imposed when a facility has been found to have provided substandard quality of care on three consecutive standard surveys.

NOTE: Termination may be imposed by the State or HCFA at any time, when appropriate.

* This is required only when a decision is made to impose alternative remedies instead of or in addition to termination.

Once the seriousness of the deficiency(ies) is determined, and the decision is made to impose remedies instead of, or in addition to, termination, the regional office, or the State Medicaid agency, or both, as determined in accordance with §7300, must select one or more remedies from the remedy category (or a HCFA approved alternative or additional State remedy) associated with the specific level of noncompliance in accordance with the visual matrix above. The remedy category to be applied against facility noncompliance will be determined by the most serious deficiency(ies) identified, i.e., deficiencies falling into the box closest to Box L. Additional factors may be considered, including but not limited to, those provided in subsection 2.

2. Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category.--Additional factors that may be considered to assist in determining which and/or how many remedy(ies) to impose within the available remedy categories for particular levels of noncompliance, include but are not limited to:

- o The relationship of one deficiency to other deficiencies;
- o The facility's prior history of noncompliance in general, and specifically with reference to the cited deficiency(ies); and
- o The likelihood that the selected remedy(ies) will achieve correction and continued compliance.

EXAMPLE: If failure to spend money is the root cause of the facility's noncompliance, then any civil money penalty that is imposed should at least exceed the amount saved by the facility by not maintaining compliance.

3. Requirement For Facility To Submit Plan of Correction.--(See also §7304.) Except when a facility has isolated deficiencies that constitute no actual harm with potential for no more than minimal harm, each facility that has a deficiency must submit an acceptable plan of correction. For a plan of correction to be acceptable, it must address the required elements provided in §7304. Those facilities having isolated deficiencies that constitute no actual harm with potential for minimal harm need not submit a plan of correction. The regional office approves plan of corrections for State-operated facilities and for validation surveys; the State approves all others. The process and timetable for HCFA's approval of plan of corrections under the continuation of payment provision is in accordance with §7600. The requirement that facilities submit a plan of correction can be found in §7304.

F. When To Select Remedy From Specific Remedy Category.--

1. Category 1.--Select at least one remedy from category 1 when there:

- o Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- o Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 1 may be applied to any deficiency.

CATEGORY 1 remedies include:

- o Directed plan of correction (see §7500);
- o State monitoring (see §7504); and
- o Directed in-service training (see §7502).

NOTE: The State, as an agent of HCFA or the State Medicaid agency may, impose one or more category 1 remedies, as authorized by HCFA or the State Medicaid agency, in accordance with §7314.

2. Category 2.--Select at least one remedy from category 2 when there are:

- o Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- o One or more deficiencies (regardless of scope) that constitute actual harm that is not immediate jeopardy.

EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 2 may be applied to any deficiency.

NOTE: The State Medicaid agency does not have the statutory authority to impose the remedy of denial of payment for all Medicare and/or Medicaid residents. The State, as an agent of HCFA or the State Medicaid agency, may provide notice of imposition of denial of payment for new admissions, as authorized by HCFA and/or the State Medicaid agency, in accordance with §7314.

CATEGORY 2 remedies include:

- o Denial of payment for all new Medicare and/or Medicaid admissions (see §7506);
- o Denial of payment for all Medicare and/or Medicaid residents, imposed by the Regional office (see §7508);
- o Civil money penalties of $50 - $3,000 per day of noncompliance (see §7510); and
- o Civil money penalties of $1,000 - $10,000 per instance of noncompliance (see §7510).

3. Selection From Category 3.--Termination or temporary management, or both, must be selected when there are one or more deficiencies that constitute immediate jeopardy to resident health or safety. A civil monetary penalty of $3,050 - $10,000 per day or a civil money penalty of $1,000 - $10,000 per instance may be imposed in addition to the remedies of termination and/or temporary management. Temporary management is also an option when there are widespread deficiencies constituting actual harm that is not immediate jeopardy.

NOTE: Termination may be imposed by the State or HCFA at any time, when appropriate.

* This is required only when a decision is made to impose alternative remedies instead of or in addition to termination.

Once the seriousness of the deficiency(ies) is determined, and the decision is made to impose remedies instead of, or in addition to, termination, the regional office, or the State Medicaid agency, or both, as determined in accordance with §7300, must select one or more remedies from the remedy category (or a HCFA approved alternative or additional State remedy) associated with the specific level of noncompliance in accordance with the visual matrix above. The remedy category to be applied against facility noncompliance will be determined by the most serious deficiency(ies) identified, i.e., deficiencies falling into the box closest to Box L. Additional factors may be considered, including but not limited to, those provided in subsection 2.

2. Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category.--Additional factors that may be considered to assist in determining which and/or how many remedy(ies) to impose within the available remedy categories for particular levels of noncompliance, include but are not limited to:

- o The relationship of one deficiency to other deficiencies;
- o The facility's prior history of noncompliance in general, and specifically with reference to the cited deficiency(ies); and
- o The likelihood that the selected remedy(ies) will achieve correction and continued compliance.

EXAMPLE: If failure to spend money is the root cause of the facility's noncompliance, then any civil money penalty that is imposed should at least exceed the amount saved by the facility by not maintaining compliance.

3. Requirement For Facility To Submit Plan of Correction.--(See also §7304.) Except when a facility has isolated deficiencies that constitute no actual harm with potential for no more than minimal harm, each facility that has a deficiency must submit an acceptable plan of correction. For a plan of correction to be acceptable, it must address the required elements provided in §7304. Those facilities having isolated deficiencies that constitute no actual harm with potential for minimal harm need not submit a plan of correction. The regional office approves plan of corrections for State-operated facilities and for validation surveys; the State approves all others. The process and timetable for HCFA's approval of plan of corrections under the continuation of payment provision is in accordance with §7600. The requirement that facilities submit a plan of correction can be found in §7304.

F. When To Select Remedy From Specific Remedy Category.--

1. Category 1.--Select at least one remedy from category 1 when there:

- o Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- o Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 1 may be applied to any deficiency.

CATEGORY 1 remedies include:

- o Directed plan of correction (see §7500);
- o State monitoring (see §7504); and
- o Directed in-service training (see §7502).

NOTE: The State, as an agent of HCFA or the State Medicaid agency may, impose one or more category 1 remedies, as authorized by HCFA or the State Medicaid agency, in accordance with §7314.

2. Category 2.--Select at least one remedy from category 2 when there are:

- o Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- o One or more deficiencies (regardless of scope) that constitute actual harm that is not immediate jeopardy.

EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 2 may be applied to any deficiency.

NOTE: The State Medicaid agency does not have the statutory authority to impose the remedy of denial of payment for all Medicare and/or Medicaid residents. The State, as an agent of HCFA or the State Medicaid agency, may provide notice of imposition of denial of payment for new admissions, as authorized by HCFA and/or the State Medicaid agency, in accordance with §7314.

CATEGORY 2 remedies include:

- o Denial of payment for all new Medicare and/or Medicaid admissions (see §7506);
- o Denial of payment for all Medicare and/or Medicaid residents, imposed by the Regional office (see §7508);
- o Civil money penalties of $50 - $3,000 per day of noncompliance (see §7510); and
- o Civil money penalties of $1,000 - $10,000 per instance of noncompliance (see §7510).

3. Selection From Category 3.--Termination or temporary management, or both, must be selected when there are one or more deficiencies that constitute immediate jeopardy to resident health or safety. A civil monetary penalty of $3,050 - $10,000 per day or a civil money penalty of $1,000 - $10,000 per instance may be imposed in addition to the remedies of termination and/or temporary management. Temporary management is also an option when there are widespread deficiencies constituting actual harm that is not immediate jeopardy.

CATEGORY 3 remedies include:

- o Temporary management (see §7550);
- o Termination (see §7556);
- o Civil money penalties of $3,050 - $10,000 per day of noncompliance optional, in addition to the remedies of termination and/or temporary management (See §7510); or
- o Civil money penalties of $1,000 - $10,000 per instance of noncompliance optional (see §7510).

NOTE: Termination may be imposed by the State Medicaid agency or the regional office at any time, when appropriate. Transfer of residents or transfer of residents with closure of facility will be imposed by the State, as appropriate. Although temporary management must be imposed when there is a finding of immediate jeopardy (and termination is not sought), temporary management may be imposed for lesser levels of noncompliance.

7410. LIFE SAFETY CODE ENFORCEMENT GUIDELINES FOR SKILLED NURSING FACILITIES AND NURSING FACILITIES

A. Application of the Enforcement Regulations to Life Safety Code Surveys Conducted in Skilled Nursing Facilities and Nursing Facilities.--Skilled nursing facilities and nursing facilities must meet the requirements at 42 CFR Part 483, Subpart B, in order to receive payment under Medicare or Medicaid. To certify a skilled nursing facility or nursing facility, complete at least a Standard Health Survey and a life safety code survey. Included in the nursing home enforcement regulations at 42 CFR Part 488, Subpart F, are provisions which are also applicable to life safety code surveys.

The specific requirement for life safety code is found at 42 CFR 483.70(a) life safety from fire. A facility may meet this requirement by complying with the prescriptive requirements of the 1985 edition of the life safety code, by waivers of the prescriptive requirements, or by the Fire Safety Evaluation System. The Fire Safety Evaluation System is an equivalent system acceptable to HCFA as the authority having jurisdiction. Some existing facilities may be "grandfathered" under earlier editions of the life safety code or its equivalent Fire Safety Evaluation System. These instructions do not require the completion of a Fire Safety Evaluation System (State regulations may restrict its use).

This instruction is applicable when completing Form HCFA 2786 - Fire Safety Survey Report forms in long term care facilities.

B. Life Safety Code Scope and Severity Determination.--After a life safety code survey is completed, the life safety code surveyor will use the following guidance to decide the level of scope and severity of the resulting deficiencies and the appropriate enforcement action. The definitions below are quite similar to those used for health surveys but have been modified, where appropriate, to be applicable to life safety code surveys.

1. Scope Levels.--The scope of the deficiency reflects the pervasiveness of the deficiency throughout the facility.

Scope is **isolated** when one or a very limited number of residents or employees is/are affected and/or a very limited area or number of locations within the facility are affected.

Scope is a **pattern** when more than a very limited number of residents or employees are affected, and/or the situation has occurred in more than a limited number of locations but the locations are not dispersed throughout the facility.

Scope is **widespread** when the problems causing the deficiency are pervasive (affect many locations) throughout the facility and/or represent a systemic failure that affected, or has the potential to affect, a large portion or all of the residents or employees.

2. Severity Levels.--The severity of the deficiency reflects the impact the deficiency has on the fire safety of the individual. We define four severity levels as follows:

o **Level 1 - No actual harm with potential for minimal harm:** A deficiency that has the potential for causing no more than a minor negative impact on the resident(s) or employees.

o **Level 2 - No actual harm with a potential for more than minimal harm that is not immediate jeopardy:** Noncompliance with the requirements of the life safety code that results in the potential for no more than minimal physical, mental, and/or psychosocial harm to the resident or employee and/or that result in minimal discomfort to the residents or employees of the facility, but has the potential to result in more than minimal harm that is not immediate jeopardy.

o **Level 3 - Actual harm that is not immediate jeopardy:** Noncompliance with the requirements of the life safety code that results in actual harm to residents or employees that is not immediate jeopardy.

o **Level 4 - Immediate jeopardy to resident health or safety:** Noncompliance with the requirements of the life safety code that results in immediate jeopardy to resident or employee health or safety in which immediate corrective action is necessary because the provider's noncompliance with one or more of those life safety code requirements has caused, or is likely to cause, serious injury, harm, impairment or death to a resident receiving care in a facility or an employee of the facility.

The determination of the level of scope and severity when a facility has life safety code deficiencies should be based on the impact the life safety code deficiencies have on the overall level of life safety in the facility. This is because nearly all life safety code requirements deal with safety from harm due to fire. Each instance of threat in a facility can compound attempts at containment, extinguishment, evacuation and/or overall safety. Like health deficiencies, for which they make a scope and severity determination for each deficiency, the survey agency should make a scope and severity assessment for each life safety code deficiency.

This determination should include the likelihood of harm from a fire incident and/or the likelihood of the spread of fire in the facility from any one incident. Consideration in this determination may include, but is not limited to, whether the facility is sprinklered or unsprinklered, the facility's construction type and any special fire protection features the facility may have.

C. Survey Coordination and Data Entry.--States vary in the coordination of their life safety code and health surveys (see §2700C). While some States schedule the two surveys to occur simultaneously, in other States they occur at different times. In order to complete data submissions in a timely manner, yet give operational flexibility, input of the life safety code survey data of long term care facilities should take place no later than 60 days after the conclusion of the long term care survey. There is no prescribed order of the life safety code survey and health surveys; either may precede the other. Some surveys are conducted by the same team, while it is more typical that different teams are responsible for each.

D. Guidance on Enforcement Remedies.--If a facility does not meet the life safety code requirements at 42 CFR 483.70(a), or the Fire Safety Evaluation System does not show an equivalent level of fire safety, or no Fire safety evaluation system is completed, then the State would determine the scope/severity level for the life safety code deficiencies found on the life safety code survey to decide the enforcement remedies available. The pertinent procedures are found at §§7301 through 7400. If the facility does not meet the requirements at 42 CFR 483.70(a), but the facility shows an equivalent level of fire safety after completion of the Fire Safety Evaluation System, then the facility is found in substantial compliance.

If, after 3 months from the health survey, the facility has not achieved substantial compliance, the denial of payment for new admissions sanction takes effect (see 42 CFR 488.417).

All deficiencies cited at 42 CFR 483.70(a) that do not constitute immediate jeopardy must be corrected within 6 months. A provider's failure to achieve compliance within 6 months will result in termination. (Immediate jeopardy deficiencies will result in termination within 23 days if the facility does not remove the threat to resident and employee safety by then.)

HCFA's revisit policy can be found in §7317. The scope and severity grid can be found in §7400.

E. Imposition of Remedies.--The survey agency will follow one of two possible enforcement approaches. Option 1 is the process by which one enforcement track and set of timeframes is followed for all deficiencies, regardless of whether they are life safety code deficiencies or health deficiencies. Option 2 is the process by which two tracks and two sets of timeframes are used for deficiencies, i.e., one for the life safety code survey and one for the health survey. (Both options are predicated on the assumption that we have not waived one or more life safety code requirements.)

If the life safety code and health survey occur together or no more than 7 days apart, Option 1, which we depict below, should be followed. Timeframes are combined and notices can be combined at the discretion of the survey agency.

OPTION 1

Health survey		Life safety code survey
Day 1		Day 1
Health survey 1st month		Life safety code survey 1st month
Health survey 2nd month		Life safety code survey 2nd month
Health survey 3rd month	- - denial of payment if any - - Noncompliance remains*	Life safety code survey 3rd month
Health survey 4th month		Life safety code survey 4th month
Health survey 5th month		Life safety code survey 5th month
Health survey 6th month	- - termination if any - - - - - Noncompliance remains*	Life safety code survey 6th month

* either health deficiencies or life safety code deficiencies or both

If the life safety code and health surveys occur more than 7 days apart, Option 2, which we depict below, should be used. Time frames and notices are separate for each survey.

OPTION 2

Health survey		Life safety code survey
Day 1		Day 1
Health survey 1st month		Life safety code survey 1st month
Health survey 2nd month		Life safety code survey 2nd month
Health survey - - 3rd month	denial of payment if any - - Noncompliance remains*	Life safety code survey 3rd month
Health survey 4th month 4th month		Life safety code survey
Health survey 5th month		Life safety code survey 5th month
Health survey - - 6th month	termination if Noncompliance remains*	Life safety code survey 6th month - Life safety code survey-termination if Noncompliance remains**

* health deficiencies
** life safety code deficiencies

F. Life Safety Code Survey Waiver Guidance.--The authority to grant waivers of life safety code provisions is found at §1819(d)(2)(B)(I) of the Social Security Act.

The provision states "The Secretary may waive, for such periods as he deems appropriate, specific provisions of such Code which if rigidly applied would result in unreasonable hardship upon a facility, but only if such waiver would not adversely affect the health and safety of the residents or personnel, . . ." The facility must document to the survey agency that there will be no adverse effect on the health and safety of the residents and employees of the facility and that compliance would result in an unreasonable hardship on the facility for each specific code provision recommended for a waiver.

The above authority to grant life safety code waivers does not include other Physical Environment requirements at 42 CFR 483.70 unless specifically provided for. Refer to State Operations Manual §7014 for further guidance of non-life safety code requests for waivers or variations.

We will classify waivers into two groups: temporary waivers, for a defined time period; and continuing waivers, which are of indeterminate duration.

1. Temporary Waiver.--A temporary waiver for a defined time period may be considered for a finding for which corrective action will take more than 90 days to complete. If a waiver is granted during that time, we will not impose sanctions under the long term care enforcement regulations. Examples of the type of corrective action that could warrant a temporary waiver could include installation of a sprinkler system, or a smoke barrier. Additional examples of deficiencies which could warrant such waivers include the obstruction of exiting, penetrations of smoke barriers, and increased travel distances to exits due to new construction or remodeling of a wing of a facility. In these cases, the waiver would be for a reasonable period of time for construction activities, including planning and design. The waiver documentation submitted by the facility for approval would include a timetable with milestone dates of major activities to correct the deficiency that the surveyor could monitor on any subsequent follow-up visits. We would not envision extensions and modifications of this timetable except under extreme circumstances. Failure of the facility to follow the timetable and the milestones established in the approved temporary waiver would subject the facility to the remedies prescribed in the enforcement regulations. If the construction activities are completed within the agreed upon timetable and the deficiency is corrected, the existence of the waiver is no longer cited on the Form HCFA-2567, Statement of Deficiencies and Plan of Correction.

When the temporary waiver of life safety code requirements is in effect, the facility should have increased fire safety awareness. This increased fire safety awareness may include the establishment of interim safety measures such as a fire watch during construction, an increased number of fire drills and training of staff at the facility, or other measures that would provide an increased measure of fire protection.

2. Continuing Waivers.--We grant continuing waivers of a specific life safety code requirement when the noncompliance cannot be corrected without an unreasonable financial hardship on the facility and does not pose a threat to residents' health and safety. The State cites the deficiency on each annual survey although they do not expect it to be corrected by the facility due to the existence of the waiver. Examples of this type of finding may include improper corridor width either before or after remodeling, a dead-end corridor longer than the specified life safety code length, a specific construction type not met, a noncompliant interior finish type, excessive exit travel distance, or waiting areas open to the corridor in a non-sprinklered facility. HCFA grants waivers after an evaluation of the specific life safety code deficiency cited and its impact on the life safety of the facility.

A waiver of a life safety code requirement that cannot be corrected and that is likely to be cited on each future life safety code survey may be given for more than one year or survey interval. For example, HCFA could give a waiver for a 3-year period after which the State reviews it during the life safety code survey and if the waiver is still appropriate extend it for another 3-year period. The survey agency cites the deficiency on the annual survey and on the Form HCFA-2567, Statement of Deficiencies and plan of correction, but they review the waiver only after the 3-year period expires. The plan of correction, submitted by the facility for that deficiency would cite the existence of a waiver.

3. Enforcement and Waived Life Safety Code Requirements.--For those life safety code requirements which HCFA has temporarily waived, the following enforcement timetable should be used:

ENFORCEMENT TIMETABLES

Day 1: **The date of the follow-up survey to determine if they have met the plan of correction.** This date can be no sooner than the provider's projected correction date, indicated on an approved plan of correction. Even if they have not achieved substantial compliance, HCFA lifts the waiver on this date and the "enforcement clock" starts.*

3rd Month: **Denial of payment for new admissions**, is imposed based on life safety code noncompliance cited when HCFA lifts the waiver, and noncompliance continues for a 3-month period after that date.

6th Month **Termination occurs**, based on life safety code noncompliance cited when HCFA lifts the waiver, and noncompliance continues up to a 6-month period after that date.

*Day 1 can occur a substantial amount of time after the life safety code survey that originally triggered the waiver.

Remedies

7500. DIRECTED PLAN OF CORRECTION

A. Introduction.--These procedures implement the regulatory requirements in 42 CFR 488.424 for imposing a directed plan of correction. A directed plan of correction is one of the category 1 remedies the State or regional office can select when it finds a facility out of compliance with Federal requirements.

B. Purpose.--The purpose of the directed plan of correction is to achieve correction and continued compliance with Federal requirements. A directed plan of correction is a plan which the State or the regional office, or the temporary manager (with State or regional office approval), develops to require a facility to take action within specified timeframes.

Achieving compliance is the provider's responsibility, whether or not a directed plan of correction is followed. If the facility fails to achieve substantial compliance after complying with the directed plan of correction, the State or regional office may impose another remedy until the facility achieves substantial compliance or is terminated from the Medicare or Medicaid programs.

C. Causes.--Use of a directed plan of correction should be dependent upon causes identified by the State, Regional office, or temporary manager. For example, a directed plan of correction may be an appropriate remedy when a facility's heating system fails. The directed plan of correction would specify that the heating system must be repaired or replaced within a specific time frame. If the cause of the noncompliance was a specific structural problem, the facility could be directed to implement identified structural repairs such as a new roof, or renovations such as replacement of rusted sinks in common bathrooms.

D. Notice of Imposition of Directed Plan of Correction.--A directed plan of correction may be imposed 15 days after the facility receives notice in non-immediate jeopardy situations and 2 days after the facility receives notice in immediate jeopardy situations. The date the directed plan of correction is imposed does not mean that all corrections must be completed by that date.

7502. DIRECTED IN-SERVICE TRAINING

A. Introduction.--These instructions implement 42 CFR 488.425. Directed in-service training is one of the remedies the State, regional office, or temporary manager can select when it finds a facility out of compliance with Federal requirements.

B. Purpose.--Directed in-service training is a remedy that may be used when the State, HCFA, or the temporary manager believe that education is likely to correct the deficiencies and help the facility achieve substantial compliance. This remedy requires the staff of the facility to attend an in-service training program. The purpose of directed in-service training is to provide basic knowledge to achieve compliance and remain in compliance with Federal requirements.

C. Appropriate Resources For Directed In-Service Training Programs.--Facilities should use programs developed by well established centers of geriatric health services education such as schools of medicine or nursing, centers for the aging, and area health education centers which have established programs in geriatrics and geriatric psychiatry. If it is willing and able, a State may provide special consultative services for obtaining this type of training. The State or regional office may also compile a list of resources which can provide directed in-service training and could make this list available to facilities and interested organizations. Facilities may also utilize the ombudState Medicaid agency program to provide training in residents' rights and quality of life issues.

D. Further Responsibilities.--The facility bears the expense of the directed in-service training. After the training has been completed, the State will assess whether compliance has been achieved. If the facility still has not achieved substantial compliance, the State Medicaid agency or the regional office may impose one or more additional remedies as specified in 42 CFR Part 488.206.

E. Notice of Imposition of Directed In-Service Training.--Directed in-service training may be imposed 15 days after the facility receives notice of non- immediate jeopardy and 2 days after the facility receives notice of immediate jeopardy.

7504. STATE MONITORING

A. Introduction.--This section is established pursuant to §§1819(h)(2)(E)(ii) and 1919(h)(2)(D)(ii) of the Act (which cross refers to §§1819(g)(4)(B) and 1919(g)(4)(B) of the Act) and 42 CFR 488.422 to provide guidance in applying the remedy of State monitoring. This section also explains when State monitoring is imposed and the qualifications for a State monitor.

B. Purpose.--A State monitor oversees the correction of cited deficiencies in the facility as a safeguard against further harm to residents when harm or a situation with a potential for harm has occurred.

C. Qualifications.--Monitors are identified by the State as appropriate professionals to monitor cited deficiencies. A monitor meets the guidelines regarding conflicts of interest in §7202 and:

- o Is an employee or contractor of the State;
- o Is not an employee or contractor of the monitored facility; and
- o Does not have an immediate family member who is a resident of the facility.

D. When to Impose State Monitoring.--The Act requires State monitoring if a facility has been found on three consecutive standard surveys to have provided substandard quality of care. Otherwise, State monitoring may be considered an optional remedy. For example, some situations in which State monitoring may be appropriate include, but are not limited to, the following:

- o Poor facility compliance history, i.e., a pattern of poor quality of care, many complaints;
- o State concern that the situation in the facility has the potential to worsen;
- o Immediate jeopardy exists and no temporary manager can be appointed;

o If the facility refuses to relinquish control to a temporary manager, a monitor may be imposed to oversee termination procedures and transfer of residents; or

o The facility seems unable or unwilling to take corrective action for cited substandard quality of care.

E. Frequency.--When State monitoring is imposed, the State appoints a monitor or monitors. Monitoring may occur anytime in a facility, e.g., 24 hours a day, 7 days a week, if necessary. In all instances, monitors have complete access to all areas of the facility, as necessary, for performance of the monitoring task. Factors used to decide how often a facility is monitored may include, but are not limited to, the following:

o The nature and seriousness of the deficiency(ies) as specified by the State; and

o The timing and frequency of when the problems occurred, i.e., mealtimes, evening shifts, daily.

Monitors may be assigned to the facility at these specific times for a specified number of days, as determined by HCFA or the State, to ensure corrective action.

F. Duration.--The remedy is discontinued when:

o The facility's provider agreement is terminated; or

o The facility has demonstrated to the satisfaction of HCFA or the State that it is in substantial compliance with the requirements and (if imposed for repeated substandard quality of care) that it will remain in substantial compliance.

Continued compliance can be demonstrated by adherence to a plan of correction which delineates what systemic changes will be made to ensure that the deficient practice will not recur and how the facility will monitor its corrective actions to ensure it does not recur.

7506. DENIAL OF PAYMENT FOR ALL NEW MEDICARE AND MEDICAID ADMISSIONS FOR SKILLED NURSING FACILITIES AND NURSING FACILITIES

A. Introduction.--Sections 1819(h) and 1919(h) of the Act and 42 CFR 488.417 provide for the denial of payment for new admissions when a facility is not in substantial compliance. Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm. Definitions and guidance on situations likely to be encountered are found in the interpretive guidelines in Appendix P. This remedy may, and in certain instances, must, be imposed by HCFA or the State Medicaid agency. Denial of payment for new admissions may be imposed alone or in combination with other remedies to encourage quick compliance. Formal notice of this remedy may also be provided by the State, as authorized by the regional office and/or the State Medicaid agency (See §7301.)

B. Optional Denial of Payment for All New Admissions.--Sections 1819(h)(2)(B)(i) and 1919(h)(2)(A)(i) of the Act and 42 CFR 488.417(a) cover the optional denial of payment for new admissions. This remedy may be imposed at any time the facility is found to be out of substantial compliance, as long as the facility is given written notice at least 2 days before the effective date in immediate jeopardy cases and at least 15 days before the effective date in non-immediate jeopardy cases. HCFA will accomplish the denial of payment remedy through instructions to the appropriate

fiscal intermediary and/or the regional office's Division of Medicaid and State Operations. States must have written procedures approved by HCFA through their State plans on how to apply the denial of payment remedy. These procedures must be approved by the regional office's Division of Medicaid and State Operations.

1. Medicare Facilities.--HCFA may deny payment to the facility for all new admissions.

2. Medicaid Facilities.--The State Medicaid agency may deny payment to the facility, and HCFA may deny Federal financial participation to the State Medicaid agency for all new admissions to the facility.

C. Mandatory Denial of Payment for All New Admissions.--Sections 1819(h)(2)(D) and (E) and 1919(h)(2)(C) and (D) of the Act and 42 CFR 488.417(b) require that, regardless of any other remedies that may be imposed, denial of payment for new admissions must be imposed when the facility is not in substantial compliance 3 months after the last day of the survey identifying the deficiency, or when a facility has been found to have furnished substandard quality of care on the last three consecutive standard surveys. (See 42 CFR 488.414.) At the discretion of HCFA or the State Medicaid agency, the denial of payment remedy may be imposed at other times singly or in conjunction with other remedies, when a facility is not in substantial compliance.

1. Medicare Facilities.--HCFA must deny payment to the facility for all new admissions.

2. Medicaid Facilities.--The State Medicaid agency must deny payment to the facility, and HCFA must deny Federal financial participation to the State Medicaid agency for all new admissions to the facility.

D. Duration and Resumption of Payments.--Generally, if the facility achieves substantial compliance and it is verified through a revisit or written credible evidence, HCFA or the State Medicaid agency must resume payments to the facility prospectively from the date it is determined that substantial compliance is achieved. However, when payment is denied for repeated instances of substandard quality of care, the remedy may not be lifted until the facility is in substantial compliance and the State or HCFA believes that the facility will remain in substantial compliance. If payment is denied for any other reason and, if a survey team finds written credible evidence that the facility corrected deficiencies or was in substantial compliance before the date the survey agency received the credible evidence, the remedy may be lifted as of that date. No payments are made for the period between the date the remedy was imposed and the date that substantial compliance was achieved. HCFA accomplishes the denial of payment remedy through written instructions to the appropriate fiscal intermediary in Medicare cases, and, in Medicaid cases, through written instructions from the regional office's Division of Medicaid and State Operations.

E. Effect of Remedy on Status of Residents Admitted, Discharged, or on Temporary Leave and Readmitted Before or After Effective Date of Denial of Payment.--The resident's status on the effective date of the denial of payment is the controlling factor in determining whether readmitted residents are subject to the denial of payment. Guidelines are as follows:

- Medicare and Medicaid residents who were admitted and discharged before the effective date of the denial of payment for new admissions are considered new admissions if they are readmitted on or after the effective date. Therefore, they are subject to the denial of payment remedy.

- Medicare and Medicaid residents admitted on or after the effective date of the denial of payment for new admissions are considered new admissions. If readmitted after being discharged, they continue to be considered new admissions, and are subject to the denial of payment remedy.

o Medicare and Medicaid residents admitted before and discharged on or after the effective date of the denial of payment for new admissions are not considered new admissions if subsequently readmitted. Therefore, they are not subject to the denial of payment.

o Medicare and Medicaid residents admitted on or after the effective date of the denial of payment for new admissions who take temporary leave are not considered new admissions when they return, but continue to be subject to the denial of payment.

o Private pay residents admitted to the facility after the effective date of the denial of payment for new admissions and then became eligible for Medicare or Medicaid, are subject to the denial of payment remedy.

o Medicare and Medicaid residents admitted before the effective date of the denial of payment for new admissions who take temporary leave before, on, or after the effective date of the denial of payment are not considered new admissions upon return and, therefore, are not subject to the denial of payment.

o Private pay residents in the facility prior to the effective date of the denial of payment for new admissions who became eligible for Medicare or Medicaid after the effective date of the denial of payment for new admissions are not subject to the denial of payment remedy.

NOTE: 1. The term "temporary leave" refers to residents who leave temporarily for any reason. If residents were not subject to a denial of payment when they went on temporary leave, the term indicates that upon return they are not considered new admissions for the purposes of the denial of payment. Therefore, the term "temporary leave" is used to justify a resumption of any interrupted payment upon re-entry into the facility.

2. Only Part A is subject to denial of payment for new admissions.

A resident who is not subject to the denial of payment sanction and who goes on temporary leave, whether or not there is a leave of absence, will not be considered a new admission for the purposes of the denial of payment sanction, upon his/her return to the facility. Any interrupted payment will be resumed. In either situation, it is expected that the resident will return to the facility following leave.

7508. SECRETARIAL AUTHORITY TO DENY ALL PAYMENT FOR ALL MEDICARE AND MEDICAID RESIDENTS

A. Introduction.--Sections 1819(h)(2)(B)(i) and 1919(h)(3)(C)(i) of the Act and 42 CFR 488.418 provide that if a facility has not met a requirement, the Secretary may deny any further payment to a facility for all Medicare residents, and to a State Medicaid agency for all Medicaid residents in a facility. This is in addition to the authority to deny payment for all new admissions discussed in §7506. Although either HCFA or the State Medicaid agency may deny payment for all Medicare and/or Medicaid new admissions as described in §7506, only HCFA has the authority to deny all payment for Medicare and/or Medicaid residents. (The State may, however, recommend that HCFA impose this remedy.) The denial of all payment remedy may be imposed at any time the facility is found to be out of substantial compliance (as defined in 42 CFR 488.301), as long as the facility is given written notice at least 2 calendar days before the effective date in immediate jeopardy cases and at least 15 calendar days before the effective date in non-immediate jeopardy cases. HCFA will provide the State with timely notification whenever it decides to impose this remedy.

Although §§1819(h)(2)(B)(i) and 1919(h)(3)(C)(i) of the Act and 42 CFR 488.418(a) provide that the Secretary may impose this remedy whenever a facility has not met a requirement, it is a severe sanction. Factors to be considered in selecting this remedy could include:

1. Seriousness of current survey findings;

2. Noncompliance history of facility; and

3. Use of other remedies that have failed to achieve or sustain compliance.

B. Duration and Resumption of Payments.--If the facility achieves substantial compliance, HCFA resumes payments to the facility prospectively from the date that it verifies as the date that the facility achieved substantial compliance. No payments are made for the period between the date the remedy was imposed and the date that HCFA verifies as the date that the facility achieved substantial compliance. When HCFA denies payment for all Medicare residents for three consecutive findings of substandard quality of care, the denial of payment may not be lifted until the facility achieves substantial compliance (as indicated by a revisit or written credible evidence acceptable to HCFA) and HCFA believes that the facility will remain in substantial compliance. If payment is denied for any other reason, when HCFA or the State finds that the facility was in substantial compliance before the date of the revisit, or before HCFA or the State received written credible evidence of substantial compliance, payment is resumed on the date that substantial compliance was achieved, as determined by HCFA.

Civil Money Penalties

7510. BASIS FOR IMPOSING CIVIL MONEY PENALTIES

The following procedures incorporate §§1819(h)(1) and (2)(B) and 1919(h)(1) of the Act and 42 CFR 488.430 through 488.444.

HCFA or the State may impose a civil money penalty for the number of days that a facility is not in substantial compliance with one or more participation requirements, or for each instance that a facility is not in substantial compliance, regardless of whether the deficiencies constitute immediate jeopardy. Additionally, HCFA or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

NOTE: The per day and the per instance civil money penalty cannot be used simultaneously during a specific survey (e.g., standard, revisit, complaint), but both may be used during an enforcement cycle, if more than one survey takes place AND the per day civil money penalty was not the civil money penalty initially imposed. However, when a per day civil money penalty is the civil monetary penalty sanction initially imposed, a per instance civil money penalty cannot be imposed on a subsequent survey of the same enforcement cycle.

A civil money penalty is a valuable enforcement tool because it can be imposed, under certain circumstances, for each day of noncompliance when a provider is out of compliance with the participation requirements or for each instance of noncompliance. If imposed, a provider cannot avoid the remedy. The civil money penalty may be imposed when a facility is given an opportunity to correct and a revisit finds that the facility is not in substantial compliance. However, a menu of remedies from which to choose exists, and a civil money penalty may not be the most appropriate

choice of a remedy in every situation of noncompliance. It may be most appropriate to a civil money penalty for a situation in which a facility is not given an opportunity to correct, a situation in which immediate jeopardy exists, or a situation of serious noncompliance for which a facility may be given an opportunity to correct. Serious noncompliance includes deficiencies which fall at levels G, H, or I, or a finding of substandard quality of care. States and regional offices are encouraged to develop methods to ensure that civil money penalty amounts are applied consistently within the broad ranges identified at 42 CFR 488.408. (See §7400 for an explanation of deficiencies which fall at levels D, E, F, G, H, and I.)

A. Past Noncompliance.--HCFA or the State should consider imposing a civil money penalty as a remedy for serious past noncompliance which would include immediate jeopardy that is corrected at the time of the current survey. However, if the facility has been out of compliance with a regulatory requirement between two surveys which found it in compliance, the past noncompliance should not be cited by the survey team if a quality assurance program is in place and has corrected the noncompliance. An exception to this policy should be made in cases of egregious past noncompliance, such as when the noncompliance has caused the death of a resident.

NOTE: Either the per day or per instance civil money penalty may be selected as an enforcement remedy when serious noncompliance is identified. However, when it is difficult to accurately establish when the noncompliance began or was corrected, the selection of the per instance civil money penalty may be the most appropriate choice.

B. Documenting Past Noncompliance.--Noncompliance identified between surveys is entered on the Form HCFA-2567. The deficiency tags are entered at the bottom of the form under the heading "past noncompliance" at Tag 698. The dates of the past noncompliance are noted in the summary statement of deficiencies. All appropriate information is entered on the Form HCFA-462L.

7511. PER INSTANCE CIVIL MONEY PENALTY AND NO OPPORTUNITY TO CORRECT

Regardless of whether or not a per day civil money penalty has already been imposed and regardless of whether or not a facility is otherwise being given an opportunity to correct its other noncompliance, it will not be given an opportunity to correct the deficiencies against which a per instance has been imposed (see §7304).

7512. COMPLIANCE WITH SECTION 1128A OF THE ACT

The regional office consults with the regional attorney's office to ensure compliance with §1128A of the Act and Department of Justice requirements. Section 1128A of the Act requires HCFA to offer a hearing before collecting, but not imposing, a civil money penalty.

For nuring facilities, §1919(h)(2) of the Act requires States to implement remedies by either State statute or regulation. State law may include additional specific requirements which must be met. Section 1919(h)(8) of the Act requires States to offer a hearing before collecting a civil money penalty.

7514. SPECIAL PROCEDURES REGARDING COMPLIANCE DECISION AND OVERLAP OF REMEDIES

If HCFA and the State Medicaid agency both want to impose civil monetary penalties on a facility, only HCFA's civil money penalty is imposed. Special procedures specified in §7807 implement the provisions of 42 CFR 488.452 regarding whether the State or Federal remedy decision takes precedence in non-immediate jeopardy situations involving non-State operated nursing facilities and dually participating facilities.

7516. DETERMINING AMOUNT OF CIVIL MONEY PENALTY

A. Range of Penalty Amounts.--Civil money penalties are imposed in increments of $50.00.

1. Lower Range of Penalty Amounts for Per Day Civil Money Penalty.--Penalties in the range of $50 to $3,000 per day may be imposed when immediate jeopardy does not exist, but the deficiencies either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm. A civil money penalty may not be less than $50.00 per day.

2. Upper Range of Penalty Amounts for Per Day Civil Money Penalty.--Penalties in the range of $3,050 to $10,000 per day may be imposed for deficiencies constituting immediate jeopardy. Penalties may also be in the upper range of penalty amounts for deficiencies when immediate jeopardy does not exist if a penalty in the lower range of penalty amounts was previously imposed and the deficiencies in the same regulatory grouping are repeated. Repeated deficiencies are defined in subsection C.2.

3. Range of Per Instance Penalty Amounts.--Penalties in the range of $1,000 to $10,000 per instance(s) may be imposed for noncompliance that constitutes actual harm, or for noncompliance that has the potential for more than minimal harm. The terminology "per instance" is not used to suggest that only one instance of noncompliance may be assigned a civil money penalty. There can be more than one instance of noncompliance identified during a survey where the State utilizes the per instance civil money penalty as an enforcement remedy. The total dollar amount of the civil money penalty for the instance or multiple instances of noncompliance may not exceed $10,000, and may not be less than $1,000 per instance.

NOTE: In situations of past noncompliance, the per day or per instance civil money penalty may be selected as an enforcement remedy when serious noncompliance is identified. (See §7510.)

B. Factors Affecting Amount of Penalty.--(Also see guidance provided in §7400.) Once the decision has been made to impose a civil money penalty for facility noncompliance, whether the noncompliance is current or past, the following factors are considered in determining the specific amount of the civil money penalty to impose within the appropriate range:

1. The facility's history of noncompliance, including repeated deficiencies. This information may be obtained from:

a. Provider files maintained in the State or the regional office from the current survey and the past three surveys, and

b. Facility specific reports maintained in the Online Survey, Certification and Reporting System from the current survey and the past three surveys;

2. The facility's financial condition. The following is only a suggested list of sources for this information and is not intended to represent exclusive or mandatory sources of information:

a. Resources available to the provider;

b. Information furnished by the provider (e.g., in the letter notifying the facility that civil money penalties are being imposed, ask the facility to provide any information that could have an impact on the amount of the civil money penalty);

c. Consultation with the fiscal intermediary (e.g., ask for pertinent facility financial information before HCFA sends the notice to the facility to impose civil money penalties); or

d. Consultation with the State Medicaid agency (e.g., ask for pertinent facility financial information before HCFA sends the notice to impose civil money penalties);

3. Seriousness and scope of the deficiencies. Appendix P of the State Operations Manual provides guidance regarding the seriousness and scope of the identified deficiencies. Appendix Q of the State Operations Manual provides guidance in determining the existence of immediate jeopardy.

4. The relationship of one deficiency to other deficiencies.

5. The facility's degree of culpability. A facility is always responsible for the health and safety of its residents. A facility is culpable if noncompliance causing harm or placing a resident at risk of harm is intentional or is a product of neglect, indifference, or disregard.

6. Any other remedies being imposed in addition to the civil money penalty.

C. Changing Amount of Civil money penalty.--The amount of the civil money penalty may be decreased or increased in accordance with the following procedures.

NOTE: When the per instance civil money penalties has been selected as an enforcement remedy, the provision for changing the amount of the civil money penalty does not apply and no opportunity to correct is provided.

1. Decreasing Penalty.--If a civil money penalty is imposed for a situation of immediate jeopardy and the immediate jeopardy is removed but the noncompliance continues, HCFA or the State will shift the penalty amount to the lower range of penalty amounts.

2. Increasing Penalty.--Before the hearing, and following a revisit showing continued noncompliance, HCFA or the State may propose to increase the penalty amount for facility noncompliance, which after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

If a civil money penalty is imposed, HCFA and the State must increase the penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for deficiencies when immediate jeopardy does not exist.

3. Repeated deficiencies.-- (See 42 CFR 488.438(d)(3).) These are deficiencies found at the last standard or abbreviated standard survey for which a civil money penalty was imposed and sustained, and which are subsequently corrected and the facility is certified in compliance, but deficiencies in the same regulatory grouping of requirements are found again at the next standard or abbreviated standard survey. For example, a civil money penalty is imposed and sustained in some amount for deficiencies under Quality of Care related to hydration (see 42 CFR 483.25(j)) during a standard survey. These deficiencies are corrected at the time of the revisit. However, at the next survey, the facility has deficiencies in quality of care related to nutrition. (See 42 CFR 483.25(i).) In this situation, if a civil money penalty is imposed, it would be higher than the civil money penalty that was imposed for the Quality of Care deficiencies regarding hydration cited previously.

If the amount of the civil monetary penalty is modified, a notice is sent to the facility as quickly as possible notifying it of the revised amount of the civil monetary penalty, the date that the revised amount is effective, and an explanation for the changed amount. The revised amount is effective on the date of the revisit or survey which identifies the change in the facility's noncompliance.

The following example illustrates how the accrual is calculated when a civil money penalty is altered.

EXAMPLE: A civil money penalty is imposed for 4 days of immediate jeopardy at $3,500 per day, the amount is shifted to $1,000 per day when the immediate jeopardy is removed, and the facility is in substantial compliance with the requirements on the eleventh day. A civil money penalty is imposed for 10 days of noncompliance. The total amount of the penalty is $20,000. [($3,500x4)+($1,000 x6)=$20,000.] This revised amount is also recorded on the Adverse Action Extract (Form HCFA-462L).

7518. EFFECTIVE DATE OF CIVIL MONEY PENALTY

The per day civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by HCFA or the State. The per instance civil money penalty is for a deficiency or deficiencies within a specific survey (e.g., standard; revisit; complaint) up to a maximum of $10,000 for that specific survey. Often, the effective date of the per day civil money penalty will be the date of the survey because it may be difficult to document precisely when noncompliance begins if before the date of survey. The effective date of the per instance civil money penalty will be the date of the survey which identified the noncompliance against which it is being imposed. A civil money penalty cannot be collected until a facility has an opportunity for a hearing if it properly requests one. Allowing an effective date for the accrual of a per day civil money penalty to be as early as the date of the noncompliance permits the noncompliance to be sanctioned promptly and requires that a facility be notified promptly of the imposition of the civil money penalty. However, if there is undue delay in notifying the facility of the civil money penalty, it is possible that the effective date of the penalty could be moved to a date later than the date of the noncompliance.

7520. NOTICE OF IMPOSITION OF CIVIL MONEY PENALTY

The State notifies the facility of the possibility of a civil money penalty being imposed for noncompliance in its initial letter to the facility after the survey. The State may:

- Recommend that the regional office and/or the State Medicaid agency impose the civil money penalty promptly as a result of noncompliance found during a standard, complaint, or revisit survey;

- Recommend that a civil money penalty accrue from the date of the noncompliance as a result of a revisit substantiating the facility's failure to correct the noncompliance;

- Recommend that the regional office and/or the State Medicaid agency impose a civil money penalty for each instance that results in a deficiency during a survey; and

- Recommend a civil money penalty upon identification of past noncompliance. The specific procedures specified in §7306, Timing of civil money penalties, are followed.

NOTE: Both civil money penalties (per day and per instance) cannot be recommended for the same survey.

However, upon the regional office's and/or the State Medicaid agency's acceptance of the State's recommendation, the regional office or the State Medicaid agency issues a formal notice, as specified in '7305. The formal notice also incorporates the specific civil money penalty information below. Since the civil money penalty may start accruing as early as the date of the finding of noncompliance found during the standard survey or a complaint survey, it is important that the regional office or the State Medicaid agency send the formal notification of the imposition of the civil money penalty to the facility as quickly as possible.

A. Responsibility for Issuing Notice.--HCFA sends a written notice of the imposition of the civil money penalty when HCFA is imposing the civil money penalty on a skilled nursing facility, nursing facility, or skilled nursing facility/nursing facility. The State Medicaid agency sends a written notice of the imposition of the civil money penalty when the State Medicaid agency is imposing a civil money penalty on a non-State operated nursing facility

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B. Content of Notice.--In addition to the notice requirements in §7305, the following civil money penalty information is included:

1. The nature of the noncompliance (regulatory requirements not met);

2. The statutory basis for the civil money penalty;

3. The amount of the penalty per day of noncompliance or the amount of the penalty per instance of noncompliance during a survey;

4. The factors that were considered in determining the amount of the civil money penalty;

5. The date on which the per day civil money penalty begins to accrue;

6. A statement that the per day civil money penalty will stop accruing on the date on which the facility comes into substantial compliance or is terminated from participation in the program;

7. When the civil money penalty is collected;

8. Statement of the facility's right to a hearing and information regarding how to request a hearing; and

9. Implications of waiving the right to a hearing and information regarding how to waive the right to a hearing.

7522. DURATION OF CIVIL MONEY PENALTY

The per day civil money penalty accrues for the number of days of noncompliance from the date that the deficiency starts until the date that the facility achieves substantial compliance or, if applicable, the date of termination. For example, if a facility is found in substantial compliance or its provider agreement is terminated on May 18, the accrual of the civil money penalty stops on May 17. The per instance civil money penalty is imposed for each instance of noncompliance based on a deficiency during a specific survey. It is applied to as many instances as is deemed appropriate during a specific survey up to $10,000 total.

EXAMPLE: When the per instance civil money penalty is used on the original survey, the revisit is considered another survey to determine compliance. If noncompliance is identified and a civil money penalty appears justified, either the per instance or per day remedy may be selected.

A. Revisit Identifies New Noncompliance and Same Data Tag is Selected.--If the same data tag is selected to identify noncompliance, the State (or regional office) could choose to utilize either the per instance or per day civil money penalty as an enforcement remedy. It would not matter whether the same data tag was selected to identify the new noncompliance. The issue is whether noncompliance is present and whether the deficient practice rises to a level that will support using a civil money penalty as an enforcement remedy. For instance, noncompliance was identified at Tag 324 during the original survey, and during the revisit survey, a different problem dealing with the elopement of three residents was cited at Tag 324. The per instance or per day civil money penalty would be selected for the noncompliance identified at Tag 324. If the per instance civil money penalty was used, the amount of the civil money penalty might be influenced by factors leading to the elopement. However, only one per instance civil money penalty would be appropriate. It would not be appropriate to assign a separate civil money penalty for each of the elopements (findings) identified at Tag 324.

B. Revisit Identifies New Noncompliance and a Different Data Tag is Selected.--If the revisit identifies new deficiencies recorded using a different data tag, either a per instance or per day civil money penalty could be selected as an enforcement remedy.

C. Noncompliance Immediate Jeopardy Does Not Exist).--For noncompliance that does not pose immediate jeopardy, the per day civil money penalty is imposed for the days of noncompliance, that is, from the day the penalty starts, and this may be prior to the notice, until the facility achieves substantial compliance or the provider agreement is terminated. However, if the facility has not achieved substantial compliance at the end of 6 months from the last day of the original survey, the regional office terminates and the State may terminate the provider agreement. The accrual of the civil money penalty stops on the date that the provider agreement is terminated. For noncompliance that does not pose immediate jeopardy, the per instance civil money penalty is imposed for the number of deficiencies during a survey that the civil money penalty is deemed to be an appropriate remedy. For example, Tag 314 and Tag 312 were cited on a survey. A civil money penalty of $2,000 is imposed for F312 and a civil money penalty of $8,000 is imposed for Tag F314. Or, a civil money penalty of $10,000 is imposed for Tag F314. No civil money penalty could then be imposed for additional deficiencies because the total "per instance civil money penalty" may not exceed $10,000 for each survey.

NOTE: The per day and the per instance civil money penalty cannot be used simultaneously during a specific survey (e.g., standard, revisit, complaint), within an enforcement cycle, but both may be used during an enforcement cycle when more than one survey takes place, AND the per day civil money penalty was not the civil money penalty initially imposed. However, if a per day civil money penalty is imposed initially, a per instance civil money penalty cannot be imposed on a subsequent survey within the same enforcement cycle.

D. Noncompliance Immediate Jeopardy Exists.--For noncompliance that poses immediate jeopardy, HCFA does or the State must terminate the provider agreement within 23 calendar days after the last day of the survey which identified the immediate jeopardy if the immediate jeopardy is not removed. If the life safety code survey found the immediate jeopardy, HCFA does or the State must terminate the provider agreement within 23 days after the last day of the life safety code survey. The accrual of the per day civil money penalty stops on the date that the provider agreement is terminated. The per instance civil money penalty is limited to $10,000 per survey.

NOTE: The per day and the per instance civil money penalty cannot be used simultaneously during a specific survey (e.g., standard, revisit, complaint) within an enforcement cycle, but both may be used during an enforcement cycle when more than one survey takes place AND the per day civil money penalty was not the civil money penalty initially imposed. However, if a per day civil money penalty is imposed initially, a per instance civil money penalty cannot be imposed on a subsequent survey within the same enforcement cycle.

7524. SETTLEMENT OF CIVIL MONEY PENALTY

The regional office has the authority to settle cases at any time prior to a final administrative decision when the regional office imposed the civil money penalty. The State has the authority to settle cases at any time, prior to the evidentiary hearing decision, when the State Medicaid agency imposed the civil money penalty. If a decision is made to settle, the settlement should not be for a better term than had the facility opted for a 35 percent reduction.

7526. APPEAL OF NONCOMPLIANCE WHICH LED TO IMPOSITION OF CIVIL MONEY PENALTY

A. Facility Requests Hearing on Noncompliance Which Led to Imposition of Civil Money Penalty.--Before collecting a civil money penalty, '1128A of the Act requires the Secretary (HCFA) to conduct a hearing for a provider that properly requests one. Section 1919(h)(8) of the Act requires the State to offer a hearing before collecting a civil money penalty.

1. HCFA Imposes Civil Money Penalty.--The procedures to request a hearing specified in 42 CFR 498.40 are followed when HCFA imposes a civil money penalty on a State-operated facility, a skilled nursing facility, a dually participating facility (skilled nursing facility/nursing facility), or any other facility that has undergone a HCFA validation survey or HCFA review of the State's findings. (HCFA's review could include a paper review of the State's survey material.) The facility should send its request for a hearing to the Departmental Appeals Board with copies to the State and regional office.

2. State Imposes Civil Money Penalty.--The procedures to request a hearing specified in 42 CFR Part 431 are followed when the State imposes a civil money penalty on a non-State operated nursing facility that has neither undergone a HCFA validation survey nor a HCFA review of the State's findings resulting in a HCFA/State disagreement.

3. Review of Civil Money Penalty.--When the basis for imposing the civil money penalty exists, the Administrative Law Judge or State hearing officer (or higher administrative review authority) may not:

a. Set a civil money penalty of zero or reduce a civil money penalty to zero;

b. Review the exercise of discretion by HCFA or the State to impose a civil money penalty;

For civil money penalties, an appeal of the level of noncompliance found by HCFA in a skilled nursing facility or nursing facility is limited to situations in which a successful challenge of the issue would affect the range of civil money penalty amounts that HCFA could collect; that is, a civil money penalty imposed in the upper range of penalty amounts for a situation of immediate jeopardy. The State's conclusion about a nursing facility=s level of noncompliance must be upheld unless clearly erroneous.

B. Facility Waiver of Right to Hearing.--A facility may waive the right to a hearing in writing within 60 calendar days from the date of the notice of imposition of the civil money penalty.

If a facility waives its right to a hearing in writing within 60 calendar days from the date of the notice of imposition of the penalty, the regional office or the State Medicaid agency reduces the civil money penalty amount by 35 percent. After receipt of the waiver, the regional office or the State Medicaid agency notifies the facility of receipt of the waiver request.

If a facility does not waive its right to a hearing in accordance with specified procedures, the civil money penalty is not reduced 35 percent.

NOTE: Each time a survey is conducted and a per instance civil money penalty is imposed, the facility may exercise its waiver of right to a hearing outlined in '7526B.

After the facility comes into substantial compliance or its provider agreement is terminated, the facility is notified of the revised civil money penalty amount due.

7528. WHEN PENALTY IS DUE AND PAYABLE

A. After Final Administrative Decision.--When the regional office imposes a civil money penalty, a final administrative decision includes an Administrative Law Judge decision and review by the Departmental Appeals Board, if the facility requests a review of the Administrative Law Judge decision. Payment of a civil money penalty is due 15 days after a final administrative decision, upholding the imposition of the civil money penalty, when:

1. The facility achieved substantial compliance before the final administrative decision; or

2. The effective date of termination occurred before the final administrative decision.

B. No Hearing Requested.--Payment of a civil money penalty is due 15 days after the time period for requesting a hearing has expired and a hearing request was not received when:

1. The facility achieved substantial compliance before the hearing request was due; or

2. The effective date of termination occurred before the hearing request was due.

C. After Request to Waive Hearing.--Payment of a civil money penalty is due 15 days after receipt of the facility's written waiver of a right to a hearing when:

1. The facility achieved substantial compliance before receipt of the facility's written waiver of its right to a hearing; or

2. The effective date of termination occurred before receipt of the facility's written waiver of its right to a hearing.

D. After Substantial Compliance Is Achieved.--Payment of a civil money penalty is due 15 days after substantial compliance is achieved when:

1. A final administrative decision, upholding the imposition of the civil money penalty, is made before the facility came into substantial compliance;

2. The facility did not file a timely hearing request before it came into substantial compliance; or

3. The facility waived its right to a hearing before it came into substantial compliance. However, the period of noncompliance covered by the civil money penalty may not extend beyond 6 months from the last day of the standard health survey.

E. After Effective Date of Termination.--Payment of a civil money penalty is due 15 days after the effective date of termination, if before the effective date of termination:

1. The final administrative decision was made upholding the imposition of the civil money penalty;

2. The time for requesting a hearing has expired and the facility did not request a hearing; or

3. The facility waived its right to a hearing.

7530. NOTICE OF AMOUNT DUE AND COLLECTIBLE

The following information is included in a notice of the amount due which is sent to the facility by the entity imposing the civil money penalty after the final amount due and collectible is determined:

A. The amount of the penalty per day or the amount of the penalty per instance;

B. For the per day civil money penalty, the number of days involved;

C. The total amount due;

D. The due date of the penalty;

E. The rate of interest to be assessed on the unpaid balance beginning on the due date as follows:

1. Medicare Facility.--For Medicare, the rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the Federal Register by the Department of Health and Human Services under 45 CFR 30.13(a); or, the current value of funds rate which is published annually in the Federal Register by the Secretary of the Treasury, subject to quarterly revisions. (The regional office contacts HCFA=s Division of Accounting for the rate of interest information.)

2. Medicaid Facility.--If the State Medicaid agency imposed the civil money penalty on a Medicaid facility, the State specifies the rate of interest used.

F. Method of payment.

1. The civil money penalty is payable by check to HCFA if the check is rendered by the due date.

2. After the due date of the penalty, the regional office or the State Medicaid agency deducts the civil money penalty plus any accrued interest from money owed to the provider.

7534. DISPOSITION OF COLLECTED CIVIL MONEY PENALTY

A. Collected From Medicare Facility.--A civil money penalty collected from a Medicare facility is deposited as miscellaneous receipts of the Treasury of the United States. (See §1128A(f)(3).)

B. Collected From Medicaid Facility.--A civil money penalty collected by a State from a Medicaid facility that the State or HCFA finds deficient must be applied to the protection of the health or property of residents of nursing facilities that the State or HCFA finds deficient. (See §1919(h)(2)(A)(ii).) Some examples of appropriate uses by the State of the collected civil money penalty include:

1. State costs related to the operation of a facility pending correction of the deficiencies or closure;

2. Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents. Established procedures for the reimbursement of residents are followed; and/or

3. Payment for the cost of relocating residents to other facilities.

C. Collected From Dually Participating Facility.--A civil money penalty collected from a dually participating facility is apportioned commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue, per census data in the Online Survey, Certification and Reporting System/Online Data Input and Edit at the time of the survey.

1. The Medicare portion of the collected civil money penalty is deposited as miscellaneous receipts of the Treasury of the United States in the Fines, Penalties, and Forfeitures Account.

2. The Medicaid portion of the collected civil money penalty is returned to the State.

EXAMPLE: In a dually participating facility that has the capacity to provide care for 100 residents, 70 residents are in the facility on the date that the civil money penalty begins to accrue. Of the 70 residents, the care of 15 residents is paid for by Medicare, the care of 45 residents is paid for by Medicaid, and 10 residents pay for their own care. Thirty of the total 100 beds are empty. There are 60 Medicare and Medicaid residents. The amount of the civil money penalty is apportioned as follows: 25 percent (15/60) of the civil money penalty would be apportioned to the miscellaneous receipts of the Treasury of the United States for Medicare and 75 percent (45/60) is returned to the State to be applied to the protection of the health and property of residents of nursing facilities that the State or HCFA finds deficient.

7536. LOSS OF NURSE AIDE TRAINING AND COMPETENCY EVALUATION PROGRAM OR COMPETENCY EVALUATION PROGRAM AS A RESULT OF CIVIL MONEY PENALTY

Sections 1819(f)(2)(B) and 1919(f)(2)(B) of the Act and 42 CFR 483.151(b) use the term "assessed" to state that the approval of a nurse aide training and competency evaluation program or competency evaluation program is prohibited in a facility which, within the previous 2 years, has been assessed

a civil money penalty of not less than $5,000. Section 7809 provides additional information regarding nurse aide training and competency evaluation program and competency evaluation program disapprovals.

A. Definition of AAssessed@.--The term "assessed" is defined to reflect the fact that the civil money penalty may be revised on administrative appeal. The assessed amount of the civil money penalty is the final amount determined to be owed after a hearing, waiver or right to a hearing, or settlement.

B. Effective Date for Prohibition of Nurse aide Training and Competency Evaluation Program or Competency Evaluation Program when Civil Money Penalty of $5,000 or More Is Assessed.--If a civil money penalty of $5,000 or more is assessed on a facility as a result of noncompliance found during a survey, the effective date of the prohibition of the nurse aide training and competency evaluation program or competency evaluation program specified in the notice cannot be before the time frame for requesting a hearing has expired, or after receipt of the written waiver, or later than the date on which a civil money penalty of $5,000 or more is upheld on administrative appeal. In accordance with 42 CFR 483.151, the State notifies the program in writing, indicating the reason(s) for withdrawal of approval of the program. However, students who have started a training and competency evaluation program for which approval has been withdrawn must be allowed to complete the course.

It is possible for a facility to experience two or more separate losses of nurse aide training and competency evaluation program or competency evaluation program which could run concurrently for at least part of the same period of time. The starting time for the first loss of nurse aide training and competency evaluation program or competency evaluation program would occur after a civil money penalty of $5,000 or more is assessed and the completion of a nurse aide training and competency evaluation program or competency evaluation program course in progress. The starting time for the second loss of nurse aide training and competency evaluation program or competency evaluation program would occur after a civil money penalty of $5,000 or more is assessed. If the two periods of loss of the nurse aide training and competency evaluation program or competency evaluation program training overlap, nurse aide training and competency evaluation program or competency evaluation program will not be restored until the second 2-year loss has been completed.

7550. TEMPORARY MANAGEMENT

A. Introduction.--This remedy is established pursuant to "1819(h)(2)(A)(I), 1819(h)(B)(iii), 1919(h)(1)(A), 1919 (h)(2)(A)(iii), 1919(h)(3)(B)(I), and 1919(h)(3)(C)(iii) of the Act and 42 CFR 488.415.

B. Purpose.--A temporary manager may be imposed any time a facility is not in substantial compliance. However, when a facility's deficiencies constitute immediate jeopardy or widespread actual harm and a decision is made to impose an alternative remedy to termination, the imposition of temporary management is required. It is the temporary manager=s responsibility to oversee correction of the deficiencies and assure the health and safety of the facility's residents while the corrections are being made. A temporary manager may also be imposed to oversee orderly closure of a facility.

C. Authority of Temporary Manager.--A temporary manager has the authority to hire, terminate, or reassign staff; obligate facility funds; alter facility procedures; and otherwise manage a facility to correct deficiencies identified in the facility's operation.

D. Selection of Temporary Manager.--The State will select the temporary manager when the State Medicaid agency is imposing the remedy and will recommend a temporary manager to the regional office when HCFA is imposing the remedy. Each State should compile a list of individuals who are eligible to serve as temporary managers.

The following individuals are not eligible to serve as temporary managers:

- Any individual who has been found guilty of misconduct by any licensing board or professional society in any State;

- Any individual who has, or whose immediate family members have, any financial interest in the facility to be managed. Indirect ownership, such as through a mutual fund, does not constitute financial interest for the purpose of this restriction; or

- Any individual who currently serves or, within the past 2 years, has served as a member of the staff of the facility.

The State should investigate eligible candidates' past performance by reviewing any compliance histories in the Online Survey, Certification and Reporting System of facilities managed by the candidates, and by consulting with the long term care ombudsman, and State Medicaid agency, if appropriate. The State should reject a candidate who has demonstrated difficulty maintaining compliance in the past.

The State should select or recommend a temporary manager whose work experience and education qualifies the individual to correct the deficiencies in the facility to be managed.

E. Conditions of Temporary Management.--The facility's management must agree to relinquish control to the temporary manager and to pay his/her salary before the temporary manager can be installed in the facility.

The facility cannot retain final authority to approve changes of personnel or expenditures of facility funds and be considered to have relinquished control to the temporary manager. The temporary manager must be given access to facility bank accounts that include Medicare and Medicaid receipts.

The temporary manager's salary must be at least equivalent to the prevailing annual salary of nursing home administrators in the facility's geographic area, plus the additional costs that would have reasonably been incurred by the provider if the temporary manager had been in an employment relationship, e.g., the cost of a benefits package, prorated for the amount of time that the temporary manager spends in the facility. The State is responsible for determining what constitutes a facility's geographic area.

If the facility refuses to relinquish control to the temporary manager, the facility will be terminated within 23 calendar days of the last day of the survey if the immediate jeopardy is not removed.

F. Orienting and Supervising Temporary Manager.--The State should provide the temporary manager with an appropriate orientation that includes a review of the facility's deficiencies. The State may request that the temporary manager periodically report on the actions taken to achieve compliance and on the expenditures associated with these actions.

G. Notice of Imposition of Temporary Management.--A temporary manager may be imposed 15 days after the facility receives notice in non-immediate jeopardy situations and 2 days after the facility receives notice in immediate jeopardy situations.

H. Duration.--Temporary management continues until a facility is terminated, achieves substantial compliance and is capable of remaining in substantial compliance, or decides to discontinue the remedy and reassume management control before it has achieved substantial compliance. In the latter case, the provider faces termination.

I. Alternatives to Temporary Management.--In lieu of temporary management, the State Medicaid agency may use an acceptable alternative that it has demonstrated to HCFA's satisfaction, through an approved State plan amendment, is as effective in deterring noncompliance and correcting deficiencies as temporary management. When taking enforcement action in a State with an acceptable alternative to temporary management, the regional office may also use the alternative.

7552. TRANSFER OF RESIDENTS AND TRANSFER OF RESIDENTS WITH CLOSURE OF FACILITY

A. Introduction.--This section implements §§1819(h)(4), 1919(h)(2)(A)(iv), and 1919(h)(5) of the Act in conjunction with §1819(c)(2) of the Act and 42 CFR 488.426.

B. Responsibility for Transferring Residents.--The State has the ultimate responsibility for transferring Medicare and Medicaid residents when a facility is terminated. It is true that in some instances, the facilities may assume responsibility for the safe and orderly transfer of residents when a facility is closed or its provider agreement is terminated. However, this does not relieve the State of its ultimate responsibility to transfer residents. The goal must be to minimize the period of time during which residents are receiving less than adequate care. HCFA is specifying that transfer requirements apply to only Medicare and Medicaid residents and not to private pay residents. However, when a facility is closed, regardless of whether the closure is a result of action taken by the State or by the facility, the State may have plans available to provide assistance in the relocation of private pay residents.

C. State's Prerogative to Close Facility and Transfer Residents.--A finding of immediate jeopardy will not, in and of itself, require the State to close a facility and transfer Medicare and Medicaid residents. It could, however, result in the immediate termination of a Medicare and/or Medicaid provider agreement and the subsequent transfer of Medicare and/or Medicaid residents. During an emergency, the State can permanently or temporarily transfer residents to another facility until the original facility is able to care for its residents.

7556. TERMINATION PROCEDURES FOR SKILLED NURSING FACILITIES AND NURSING FACILITIES WHEN FACILITY IS NOT IN SUBSTANTIAL COMPLIANCE WITH PARTICIPATION REQUIREMENTS

A. Introduction.--Sections 1819(h)(4) and 1919(h)(5) of the Act and 42 CFR 488.456 and 489.53 provide for termination of skilled nursing facility and nursing facility provider agreements. 42 CFR Part 431, Subpart D, provides the appeals process for nursing facilities subject to enforcement actions by the State.

Under certain circumstances, Federal regulations provide for payment to a facility beyond the effective date of termination as follows:

- Under 42 CFR 489.55, Medicare payment is available for up to 30 days after the effective date of termination for inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who is admitted before the effective date, and home health services and hospice care furnished under a plan established before the effective date.

o Under 42 CFR 441.11, Federal financial participation may be continued for up to 30 days after the effective date of termination or expiration of a provider agreement, or after an administrative hearing decision that upholds the agency's termination or nonrenewal action, as long as the Medicaid payments are for those residents admitted to the facility before the effective date of termination or expiration, and the Medicaid agency is making reasonable efforts to transfer the residents to other facilities or to alternate care.

B. Immediate Jeopardy.--When there is immediate jeopardy to resident health or safety, the enforcing agency must complete termination procedures within 23 days from the last day of the survey which found the, immediate jeopardy if it is not removed before then. (See §7309 for time frames.) The procedure must not be postponed or stopped unless the immediate jeopardy is removed, as verified through onsite verification or review of verifiable documentation. If there is a written and timely credible allegation that the immediate jeopardy has been removed, HCFA or the State will conduct a revisit prior to termination, if possible.

C. When There Is No Immediate Jeopardy.--When there is no immediate jeopardy, the State Medicaid agency may and the regional office must terminate a facility, or the regional office must stop all Federal funding to a facility, if the facility does not achieve substantial compliance within 6 months of the date of the survey that found it to be of it to be out of compliance. When an agreement to repay was signed by a Medicare facility and the facility failed to achieve substantial compliance by the 6th month, the regional office stops funding. (See §7600 regarding continuation of payment.)

However, termination is always an option that may be imposed for any facility noncompliance regardless of whether or not immediate jeopardy is present. When considering whether to terminate a facility's provider agreement, the enforcing entity considers the many factors, particularly the facility's noncompliance history (e.g., is it consistently in and out of compliance), the effectiveness of alternative remedies when previously used and found to be, and whether the facility has failed to follow through on an alternative remedy (e.g., directed in-service training). These considerations are not all inclusive but factors to consider when determining whether termination is appropriate in a given case.

7600. CONTINUATION OF PAYMENTS DURING CORRECTION

A. Introduction.--These procedures are established pursuant to §§1819(h)(2)(C) and 1919(h)(3)(D) of the Act and are implemented at 42 CFR 488.450. States use these procedures when they determine that a non-State operated skilled nursing facility, nursing facility, or skilled nursing facility/nursing facility is not in substantial compliance with Federal participation requirements, and that an alternative remedy is preferred **in lieu** of termination. If the State decides to impose alternative remedies in addition to termination, it does NOT follow these procedures. (regional offices and State Medicaid agency use the termination procedures in §7556.)

B. Purpose.--The statute permits facilities that are not in substantial compliance to continue to participate in the Medicare and Medicaid programs for 6 months without the State Medicaid agency or regional office initiating a termination action. To avoid termination, specific criteria must be met. (See C below.)

C. Criteria for Continued Payment During Correction Period.--HCFA may continue payments to a facility that is not in substantial compliance for up to 6 months from the finding of noncompliance when immediate jeopardy does not exist and the following criteria are met:

1. The State finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

2. The State has submitted a plan of correction which is approved by the regional office; and

3. The facility (for Medicare), agrees to repay the regional office payments received if action is not taken ~~in~~ according to the plan of correction approved by the regional office.

The State recommends to the regional office how long the facility's correction period should be based on the deficiencies and the facility's plan of correction. However, the correction period should not exceed 6 months since the statute only authorizes continued payments for 6 months. The plan and timetable for corrective action are equivalent to a plan of correction.

D. Approval of Plan and Timetable for Corrective Action.--The provider must develop a plan of correction within 10 calendar days of the receipt of the statement of deficiencies. The State reviews the plan of correction and it is deemed approved unless the State notifies the facility in writing that the plan is disapproved. The State may recommend an alternative remedy (or remedies) in lieu of termination. The plan, timetable, recommendation and repayment agreement(s) must be sent to the regional office by the 25th day following the last day of survey. The regional office has 5 calendar days from the date these items are received to respond to the plan of correction. If the State is not contacted by the regional office by the 6th calendar day, the plan of correction is deemed to be approved.

E. Facility Takes Corrective Action According to Its Approved Plan of Correction and Facility Has Achieved Substantial Compliance.--Once the State has determined that a facility has made corrections according to the plan of correction and the facility has achieved substantial compliance, the facility may be certified in substantial compliance and the agreement to repay is void.

F. Facility Does Not Take Corrective Action According to Its Approved Plan of Correction and Facility Has Not Achieved Substantial Compliance.--If the facility does not take action according to its approved plan of correction and does not achieve substantial compliance by the end of the specified period, the regional office:

- Terminates a skilled nursing facility's provider agreement for Medicare; or
- Discontinues Federal funding to the skilled nursing facility for Medicare; and
- Discontinues Federal financial participation to the State for the Medicaid nursing facility.

The State Medicaid agency may terminate the nursing facility's provider agreement.

Termination or discontinuation of funding does not relieve the facility of the obligation to repay Federal funds received during the correction period.

EXAMPLE: The State finds a skilled nursing facility out of compliance with its health survey on May 15. The State recommends to the regional office that it impose alternative remedies in lieu of termination. The skilled nursing facility has agreed to repay all Federal funds if it does not make the needed corrections to achieve compliance by August 1. The agreement to repay would begin for Federal payments made on May 15. On August 1, a revisit reveals that the skilled nursing facility did not make the corrections in accordance with its plan of correction. The State would notify the regional office, and the regional office will terminate the skilled nursing facility's provider agreement after providing a 15-day notice to the facility. In addition, the skilled nursing facility would be liable to repay to the regional office all the Medicare Federal funds it received for the period May 15 - August 1.

G. Facility Takes Corrective Action According to its Plan of Correction But Facility Fails to Achieve Substantial Compliance.--The Medicare facility would not be required to repay the Federal funding received because it followed its approved plan of correction. However, because the facility failed to achieve compliance, continued Federal funding beyond 6 months would stop, and, the regional office will terminate the skilled nursing facility's provider agreement.

H. Facility Does Not Take Corrective Action According to Its Plan of Correction and Facility Has Achieved Substantial Compliance.--The facility would not be required to repay the Federal funding received because it achieved substantial compliance.

I. When State Opts for Alternative Remedies in Lieu of Termination and Criteria Are Not Met.--If termination is not sought, either by itself or along with another remedy (or remedies), or if any of the applicable criteria set forth in subsection C are not met, the facility or State Medicaid agency will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey until that date that substantial compliance is achieved.

If the State recommends an alternative remedy instead of termination and the Medicare facility refuses to sign an agreement to repay, HCFA has no authority to pay for services after the last day of the survey. If funding has ceased, the State must determine if the facility is in substantial compliance before funding can resume.

Complaints

7700. INVESTIGATION OF COMPLAINTS OF VIOLATIONS AND MONITORING OF COMPLIANCE

A. Introduction.--These procedures incorporate " 1819(g)(4) and 1919(g)(4) of the Act and 42 CFR 488.332. A State is required to describe its procedures for processing complaints in its State plan. These complaint procedures complement existing procedures in '3282 and Appendix P. The following procedures describe the steps in processing a complaint against a nursing home from receipt to closeout.

An allegation is an assertion of improper care or treatment by a Medicare, Medicaid, or Medicare/Medicaid facility that could result in the citation of a Federal deficiency. Investigation and resolution of complaints is a critical certification activity. HCFA, the SMA, and the SA are responsible for ensuring that participating facilities continually meet the participation requirements. This requires prompt review and, if necessary, onsite investigation of reports alleging noncompliance. The SA informs the RO and/or the SMA any time certification requirements are found to be out of compliance. The SA establishes written procedures and maintains adequate staff to receive, investigate, and resolve complaints.

B. Collection.--Complaints may come directly to the SA or the RO from a variety of sources including individuals receiving services, their families or representatives, and other interested parties such as private organizations. Complaints may be oral or written and complaints may be anonymous. In addition, allegations about participating nursing homes may originate from a variety of State and local agencies such as the health department or adult protective services.

The following information is obtained for every allegation:

1. Complainant's name, address, and phone number. Appropriate precautions are taken to protect a complainant's anonymity and privacy. (See '3282.E.);

2. Resident's Medicare or Medicaid number, if applicable;

3. Facility's name and address; and

4. Description of the problem, including names, places, and dates.

C. Control.--Immediately after receipt, the SA establishes a file for the allegation. A control system should be used to facilitate tracking and control of the allegation until it is entered into the OSCAR Complaint Subsystem.

D. Acknowledgement (If Complainant Is Known).--The SA promptly notifies the complainant in writing or with a telephone call that the complaint is being investigated, unless the RO or SMA originally received the allegation and has already notified the complainant. A copy of this notification is maintained with the complaint documentation. The SA does not delay acknowledgement pending an investigation unless the investigation will take place within 3 working days.

E. Using Other State Components to Investigate Complaints.--States may use a variety of State components or agencies to conduct a complaint investigation. If other components are used to conduct a complaint investigation, the SA must have a means to communicate information to these components. The SA retains the responsibility for the investigation process in order to make decisions regarding a facility's compliance or noncompliance with the participation requirements.

F. Notice.--The SA informs the RO immediately if a complaint is especially significant, sensitive, or attracting broad public or media attention. Any other early notice requirements prescribed by other State or Federal policies or interagency agreements are also considered.

G. Scheduling Investigation.--It is HCFA policy that complaint investigations be unannounced.

1. Complaint Alleges Immediate Jeopardy.--The complaint is investigated within 2 working days of receipt if the allegation involves an immediate jeopardy to resident health or safety.

2. Complaint Does Not Allege Immediate Jeopardy.--The SA, using its professional judgment, determines the timing, scope, and duration of a complaint investigation.

H. Conducting Investigation.--The SA or the RO reviews complaint allegations. If a review of the allegation concludes that a deficiency may have existed, and a determination can only be made onsite, the SA conducts a standard or an abbreviated standard survey to investigate the complaint. A survey would not be conducted if the verification of the complaint does not require an onsite survey or the complaint raises issues that are outside the purview of the Federal participation requirements.

The specific complaint procedures specified in Appendix P are followed.

I. Use of Specialized Team to Investigate Complaints.--If necessary, a specialized team may be used to investigate complaints. Team members may include, but are not limited to, an attorney, auditor, and appropriate health professionals. The specialized team is not necessarily composed of qualified surveyors. However, specialized team members provide unique talents and expertise that assist at least one qualified surveyor in identifying, gathering, and preserving documented evidence. Further information regarding the composition of the survey team is provided in '7201.

J. Investigating Allegations of Resident Neglect, Abuse, or Misappropriation of Resident Property.--If, a complaint investigation substantiates that resident abuse, neglect, or misappropriation of resident property occurred, these procedures and the procedures specified in '7702, Action on Complaints of Resident Neglect and Abuse and Misappropriation of Resident Property, are followed.

K. Noncompliance Found on Complaint Investigation.--When noncompliance with Federal participation requirements is substantiated during a complaint investigation, certification and enforcement actions are initiated in accordance with the procedures for the certification of compliance and noncompliance for SNFs and NFs. (See "7300-7319.) If a complaint investigation also identifies substandard quality of care, the procedures specified in '7906, Information Furnished to Attending Physician and State

Board, are followed. The procedures specified in '7320, Action When There Is Substandard Quality of Care, are followed if the facility has been found to have provided substandard quality of care on the last three consecutive standard surveys. Substandard quality of care is defined in 42 CFR 488.301 and in Appendix P. If a complaint investigation identifies past noncompliance for which a CMP is imposed, the procedures specified in "7510-7536, Civil Money Penalties, are followed.

L. Onsite Monitoring.--The SA conducts onsite revisits on an as necessary basis when:

1. A facility is not in substantial compliance with the requirements and is in the process of correcting deficiencies;

2. A facility has corrected deficiencies and verification of continued substantial compliance is needed; or

3. The SA has reason to question the substantial compliance of the facility with a requirement of participation.

M. No Deficiencies.--No enforcement action is required.

N. Resolution and Closeout Reporting.--

1. Documentation Forwarded.--It is the SA's responsibility to ensure that a Medicare/Medicaid Complaint Form (Form HCFA-562) and the Survey Team Composition and Workload Report (Form HCFA-670) are completed for any substantiated or unsubstantiated allegations that are investigated by means of an onsite survey, and that these records are entered into the OSCAR Complaint Subsystem. If the facility is in substantial compliance, the SA completes the relevant portions of Form HCFA-562, Form HCFA-670 and, if applicable, Form HCFA-2567 and/or Form A. When noncompliance is found, the SA completes Form HCFA-562, Form HCFA-670, Form HCFA-2567, Form HCFA-1539, and, if appropriate, Form A. The Form HCFA-462L is completed when an enforcement action is taken in response to a facility's noncompliance. The SA forwards the information and any other supporting documentation to the RO or the SMA, as appropriate.

2. Reporting Timeframe.--Timeframes for reporting are consistent with the applicable procedures specified in "7300-7319.

3. Special Reporting to RO (Deficiencies Not Cited).--If a complaint originated from the RO, the SA sends the completed Form HCFA-562 and any documentation back to the RO.

4. Notice To Complainant.--In addition to the reporting above, all complaints (substantiated and unsubstantiated) are closed out with a notice to the complainant informing the complainant of the findings and disposition of the allegation. This notice is sent reasonably soon after the investigation. A copy is retained with the complaint record.

The SA provides follow-up reports as necessary to any other appropriate parties such as the RO, the SMA, initial referring agencies, or ombudsmen. The privacy rights of the complainant are protected.

7702. ACTION ON COMPLAINTS OF RESIDENT NEGLECT AND ABUSE AND MISAPPROPRIATION OF RESIDENT PROPERTY

A. Introduction.--These procedures are based on "1819(g)(1)(C) and 1919(g)(1)(C) of the Act and 42 CFR 488.335. This protocol establishes the actions the State takes to process the receipt, review, and investigation of allegations of resident neglect and abuse and misappropriation of resident property by an individual(s) used by the facility to provide services to residents.

B. Definitions.--42 CFR 488.301 and '7001 provide definitions of abuse, neglect, and misappropriation of resident property.

C. Procedures.--

1. Additional Procedures.--The procedures specified in '7700, Investigation of Complaints of Violations and Monitoring of Compliance, and Appendix P are also followed.

2. Written Procedures.--The State must have written procedures in place to assure the timely (without undue delay) review and swift investigation of allegations of neglect and abuse and misappropriation of resident property to protect residents from harm.

D. Review of Allegation.--The State reviews all allegations of resident neglect and abuse and misappropriation of resident property regardless of the source of the complaint.

E. Investigating Allegations.--The State investigates the allegation if oral or written evidence indicates that an individual employed by the facility could have neglected or abused a resident or misappropriated a resident's property or a deficiency in one or more requirements may have occurred.

F. Factors Beyond Control of Individual.--The State must not make a finding that an individual neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

EXAMPLE: A nurse aide could not be found negligent for not providing clean bed and bath linens to a resident if the facility had no clean bed and bath linens available. However, the facility is responsible for providing clean bed and bath linens to residents.

G. Notification Procedures.--If the State makes a preliminary determination, based on oral or written evidence and its investigation, that resident neglect, abuse, or misappropriation of property has occurred, the State completes the following notification procedures:

1. Individuals Notified.--The State notifies the following in writing within 10 working days of the investigation:

a. Individual(s) implicated in the investigation; and

b. The current administrator of the facility in which the incident occurred.

2. Notice Information.--The following information is included in the notice:

a. Nature of the allegation (specific facts);

b. Date and time of the occurrence;

c. A statement that the individual implicated in the investigation has a right to a hearing and must request the hearing within 30 days from the date of the notice. (Provide the individual with the specific information needed to request a hearing, such as, the name and address of a contact in the State to request a hearing.);

d. Statement that if the individual fails to request a hearing in writing within 30 days from the date of the notice, the presumed substantiated findings will be reported to the nurse aide registry or the appropriate licensure authority;

e. The intent to report findings substantiated by a hearing in writing to the nurse aide registry and/or to the appropriate licensure authority;

f. Consequences of waiving the right to a hearing;

g. Consequences of a finding through the hearing process that the resident abuse or neglect or misappropriation of property did occur; and

h. Right of the accused individual to be represented by an attorney at the individual's own expense.

H. Conduct of Hearing.--

1. Timeframe to Complete Hearing.--The State must complete the hearing and the hearing record within 120 days from the day it receives the request for a hearing.

2. Hearing Location.--The State must hold the hearing in a manner consistent with State practice at a reasonable place and time convenient for the individual.

I. Reporting Findings.--If the individual waives the right to a hearing or the time to request a hearing has expired, or if the hearing finding is that the individual neglected or abused a resident or misappropriated a resident's property, the substantiated findings must be reported in writing within 10 days to:

1. The individual;

2. Current administrator of the facility in which the incident occurred;

3. The administrator of the facility that currently employs the individual, if it is not the same facility in which the incident occurred;

4. Applicable licensing authorities; and

5. The nurse aide registry for nurse aides as specified in 42 CFR 483.156 and discussed in '4141. (Section 4141 discusses the function of the registry, the information contained in the registry, and responsibility for the registry.)

J. Reporting Findings to Nurse Aide Registry.--The SA must include the substantiated findings in the nurse aide registry.

1. Timeframe for Reporting to Nurse Aide Registry.--The SA must include the substantiated findings of abuse, neglect, or misappropriation of resident property by a nurse aide within 10 working days of the substantiated findings.

2. Information Submitted to Nurse Aide Registry.--The following information must be included and remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death.

a. Documentation of the investigation, including the nature of the allegation and the evidence that led to the conclusion that the allegation was valid;

b. The date of the hearing, if the individual chose to have one, and its outcome; and

c. A statement by the individual disputing the allegation if the individual chose to make one.

3. Removal of Information From Registry.--The registry removes entries for individuals who have performed no nursing or nursing related services for 24 consecutive months, unless the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of resident property.

K. Facility Compliance With Requirements.--The SA promptly reviews the results of all complaint investigations and determines whether a facility has violated any participation requirements. If the determination is that the facility is not in substantial compliance with the requirements, the SA documents the noncompliance on the appropriate HCFA forms and initiates appropriate certification and enforcement actions with respect to a facility's participation in Medicaid, Medicare, or Medicare/Medicaid.

Program Management

7800. CONSISTENCY OF SURVEY RESULTS

A. Introduction.--This section provides guidance to the regional office and State for the development and implementation of programs to measure accuracy and improve consistency in the application of survey results and enforcement remedies, pursuant to §§1819(g)(2)(D) and 1919(g)(2)(D) of the Act and 42 CFR 488.312.

B. Measuring Consistency.--These programs should measure the uniformity of survey findings as well as remedy recommendations and enforcement actions as stipulated by the Statute. Such programs may include:

- o Quality assurance or continuous quality improvement teams; and
- o Outside consultation and evaluation.

However, HCFA does not want to limit the types of programs the regional offices and States use to fulfill this requirement. Additionally, HCFA encourages the regions and States to share with each other innovative and unique methods used to measure consistency.

C. Additional Instruction.--The regional office should periodically review and evaluate the programs the States are implementing.

7801. SANCTIONS FOR INADEQUATE STATE SURVEY PERFORMANCE

A. Introduction.--The imposition of sanctions for inadequate State survey performance in skilled nursing facilities and nursing facilities is mandated by §§1819(g)(3)(C) and 1919(g)(3)(C) of the Act and 42 CFR 488.318 and 488.320. This section outlines the definition of inadequate survey performance, lists the performance standards as required in the 1864 agreement, and explains HCFA's evaluation process to determine if performance standards have been met. This section also sets out the sanctions available and the State's appeal rights, both formal and informal, when HCFA has imposed sanctions.

B. Purpose.--The sanctions described in subsection D represent two categories of enforcement responses. The first category is "remedies" which is intended to assist States in improving their long term care survey performance. The second category is "sanctions" which would generally be employed after remedies have been tried and a State has not been successful in adequately performing its survey functions. The purpose of remedies and sanctions is to work with States having difficulty in correcting problems, resorting to reduction in funding and contract responsibilities only as a last resort.

C. Definition of Inadequate State Survey Performance.--HCFA considers survey performance to be inadequate if the State:

1. Demonstrates a pattern of failure to:

- o Identify deficiencies, and the failure cannot be explained by changed conditions in the facility or other case specific factors;
- o Cite only valid deficiencies (i.e., the State cites unfounded deficiencies);
- o Conduct surveys in accordance with the requirements of this Chapter;

o Use Federal standards, protocols, and the forms, methods, procedures, policies and systems specified by HCFA in instructions;

o Utilize enforcement actions to assure continued compliance;

o Input online data timely and accurately;

o Conduct surveys in accordance with required time frames;

o Respond to complaints in accordance with requirements;

o Lead in the implementation by providers of Federally required patient assessment instruments or data sets; and/or

o Operate Federally required systems for the collection of patient assessment data.

2. Fails to identify an immediate jeopardy situation.

D. Performance Standards Include, But Are Not Limited To The Following:

1. Organization and staffing of the State survey agency to enable fulfillment of the functions required under the 1864 Agreement;

2. Surveys are planned, scheduled, conducted, and processed timely;

3. Survey findings are supportable;

4. Certifications are fully documented, and consistent with applicable law, regulations, and general instructions;

5. Current written internal operating procedures and policies are consistent with program requirements;

6. A plan of correction is requested from a provider/supplier;

7. When certifying noncompliance, adverse action procedures set forth in regulations and general instructions are adhered to;

8. Supervisory reviews and evaluations of surveyor performance are made routinely;

9. Required financial and budget reports are submitted on time and completed in accordance with general instructions;

10. All expenditures and changes to the program are substantiated to the Secretary's satisfaction;

11. Actual survey and certification activities are consistent with the annual activity plan and workload estimate approved by HCFA;

12. The performance of agencies utilized to perform specific functions under this Agreement are monitored;

13. Ongoing surveyor training programs develop and maintain surveyor proficiency;

14. Results of complaint investigations against providers and suppliers are considered in making certification decisions;

15. Scope and severity decisions for nursing home deficiencies are accurate and supportable;

16. Updates, training, and technical assistance about patient assessment instruments/data sets are supplied to providers as appropriate;

17. Federally supplied hardware and software for the system to collect patient assessments/data sets are operated in accordance with instructions;

18. The conduct and reporting of complaint investigations is timely and accurate;

19. Survey teams include surveyors with required qualifications and/or certifications;

20. Accurate and timely data is entered into online survey and certification data systems; and

21. Information on certification findings is provided to the public as required in instructions.

E. Performance Measures.--The refinement of performance measures will occur as a function of field experience. HCFA expects this to be a dynamic process and measures will not only need to be reassessed in terms of actual experience, but also to reflect major program changes and/or areas of emphasis. Accordingly, Program Memoranda will be issued, as needed, to communicate expectations and performance measures.

F. Performance Criteria.--All standards for adequate State performance will be measured against "threshold" criteria which may be expressed in quantifiable terms, or in some cases, narrative descriptors. Threshold criteria describe the point at which HCFA will impose a sanction or remedy on the State. By way of example, the threshold for failure to identify deficiencies, could be expressed (quantified) as a 20 percent disparity rate between Federal and State deficiency citations on any given Federal Survey, or the failure of a State to identify any single (one) instance of "Immediate Jeopardy" would be another quantifiable threshold. An example of threshold criteria explained in narrative terms would be applied to the standard, "The State uses the results of complaint investigations in making certification decisions." An appropriate descriptor in this instance could be: "State provider files do not reflect the appropriate documentation of complaints."

G. Available Sanctions/Remedies.--HCFA will take one or more of the following actions when there is inadequate State survey performance. When selecting remedies or sanctions, HCFA will consider the degree of culpability of a State's ability to perform due to circumstances beyond the control of the State Governor.

1. Remedies:

a. Provide for training of survey teams;

b. Directed Quality Improvement Plan;

c. Provide technical assistance on scheduling and procedural policies;

d Require the State to undertake improvements specified in a plan of correction; and

e. Provide HCFA directed scheduling.

2. Sanctions:

a. Place State on compliance for failure to follow the Medicaid State Plan;

b. Meet with the Governor and other responsible State officials;

c. Reduce Federal financial participation for survey and certification of nursing facilities, as specified in subsections H and I; and

d. Initiate action to terminate the agreement between the Secretary and the State under §1864 of the Act, either in whole or in part.

H. Imposing Sanctions Other Than Federal Financial Participation Reduction.--The regional office may use the results of Federal monitoring surveys, Federal Observational and Support surveys, the State Agency Quality Improvement Program or focused Federal reviews to identify inadequate State performance. Generally, the regional office will consider that there is inadequate State survey performance when enough survey data have been analyzed to indicate that there is a systemic problem in some aspect of State performance. However, even a single failure to identify an immediate jeopardy situation will be considered inadequate State survey performance. The regional office will select one or more sanctions appropriate to the inadequacy, but may not select Federal financial participation reduction to respond to any inadequacy other than a pattern of failure to identify deficiencies in nursing facilities. The regional office will notify the State in writing of the sanctions it plans to impose and the reasons for their imposition. (See 42 CFR 488.320(c).)

I. Reducing Federal Financial Participation for Pattern of Failure to Identify Deficiencies in Nursing Facilities.--Federal financial participation will only be reduced when the State demonstrates a pattern of failure to identify or accurately classify deficiencies in nursing facilities. The Act does not allow for imposition of this sanction when the failure to identify or accurately classify deficiencies occurs in Medicare-only facilities when the nature of the inadequacy is anything other than a failure to identify deficiencies. The regional office should use the following process to determine whether a pattern of failure to identify deficiencies in nursing facilities exists:

1. After each Federal survey/review of a nursing facility (and of a dually participating facility), the regional office should calculate the percentage of the discrete tags that were identified by the regional office but that did not appear on Form HCFA-2567. The regional office should average all percentages calculated in the State at the end of the each quarter of the fiscal year.

2. If the quarterly disparity rate is less than 20%, the regional office may impose those remedies and/or sanctions that do not result in a reduction of Federal financial participation.

3. If the quarterly disparity rate is greater than 20% in at least 3 of the last 4 quarters for which disparity rates were calculated, the regional office should confer with the State to seek the root causes of the disparities. The State will have the remainder of the quarter in which the root causes were identified as well as the succeeding quarter to correct the root causes. Federal surveys performed in the quarter following the correction period will ascertain whether the State has been successful.

If the Federal survey/review(s) yield a disparity rate of less than 20%, the regional office should not conclude that the State demonstrated a pattern of failure to identify deficiencies in nursing facilities and should not reduce Federal financial participation.

If the disparity rate is again greater than 20%, the regional office should advise the State that unless it can rebut the findings used to calculate the disparity rate, or can offer compelling reasons for the regional office to excuse the rate, the regional office intends to consider there to be a pattern of failure to identify deficiencies in nursing facilities, and to reduce the Federal financial participation made to the State during this quarter of the fiscal year as it is the quarter in which the determination of inadequate State survey performance is actually made. The regional office will calculate the amount of the Federal financial participation reduction in accordance with subsection G, and will forward this information to the Center for Medicaid and State Operations, Central Office, for processing.

J. Federal Financial Participation Reduction Formula.--To calculate the reduction in the Federal financial participation made to the State under §1903(a)(2)(D) of the Act for the survey and certification of nursing facilities, the regional office uses the formula specified in §1919(g)(3)(C) of the Act, which is 33 percent multiplied by a fraction:

1. The numerator of which is equal to the total number of Medicaid residents in those nursing facilities that HCFA found to be noncompliant during validation surveys in the quarter, but that the State found to be in substantial compliance; and

2. The denominator of which is equal to the total number of Medicaid residents in all of the nursing facilities (in the State) in which HCFA conducted validation surveys during the quarter.

NOTE: For the purposes of the formula, only Federal Oversight and Support Surveys will be considered "validation surveys." Only Medicaid beneficiaries in the nursing facilities are counted; private pay residents are excluded.

EXAMPLE: The regional office reduces a State's Federal financial participation for the first quarter of the fiscal year as a result of its failure to demonstrate during this quarter that it had remedied the root causes of failures to identify deficiencies that the regional office directed the State to correct two quarters ago.

The regional office conducted 2 Federal Oversight Support Surveys to evaluate the success of the State's corrective efforts during this quarter, one in a nursing facility with 100 Medicaid residents, and one in a skilled nursing facility/nursing facility with 90 Medicaid and 20 Medicare residents.

The regional office found the skilled nursing facility/nursing facility out of compliance while the State found it in substantial compliance. The regional office's compliance decision matched the State's in the nursing facility.

The regional office would reduce the State's Federal financial participation for the quarter by the following percentage:

$$.33 \times 90 = \frac{16\%}{100 + 90}$$

In this case, the numerator of the multiplier would be the number of Medicaid residents in the skilled nursing facility/nursing facility (90), because this is the one facility containing Medicaid residents that the State incorrectly found to be in substantial compliance. The denominator would be the number of Medicaid residents in both the nursing facility and skilled nursing facility/nursing facility (100+90), because these are the two facilities containing Medicaid residents in which Federal Oversight Support Surveys were conducted during the quarter. The number of
Medicare residents in the skilled nursing facility/nursing facility does not figure into the calculation at all.

K. Termination of the 1864 Agreement, in Whole or in Part--The 1864 Agreement may be terminated at any time by mutual written consent of the parties to the Agreement. States may terminate the Agreement at any time upon 180 days written notice to HCFA. If HCFA determines that the State is not able or willing to carry out part or all of the functions under this Agreement (including a determination that the State has fails to meet the performance standard(s) detailed in Section D), HCFA may unilaterally terminate the Agreement in whole or in part or otherwise limit or decrease its scope.

L. Informal Dispute Resolution.--In the regional office's notice to the State of its determination of inadequate State survey performance and its intent to impose sanctions, the regional office will offer the State an opportunity to dispute the determination. The State must submit its request in writing along with information that refutes the apparent inadequacy. The informal dispute resolution process will be conducted by one level above the decision-maker. When sanctions are imposed as described in G.2 of this section, a State is entitled to Consortium Administrator review.

M. Appeal of Federal Financial Participation Reduction.--When a State is dissatisfied with HCFA's determination to reduce Federal financial participation, the State may appeal the determination to the Departmental Appeals Board, using the procedures specified in 45 CFR Part 16.

7803. EDUCATIONAL PROGRAMS

A. Introduction.--This section implements §§1819(g)(1) and 1919(g)(1) of the Act and 42 CFR 488.334.

B. Purpose.--The purpose of this section is to ensure that long term care facility staff and residents (and their representatives) are knowledgeable regarding current regulations, procedures, and policies relative to survey, certification, and enforcement processes.

C. Methodology.--The development of educational programs and the methods of presentation are within the purview of the agency providing the training as long as the programs cover long term care regulations and the survey and enforcement process.

D. Suggested Training Modalities.--Suggested training modalities include the following:

- Video tapes;
- Satellite communication;
- Newsletters developed by the State;
- Formal presentations; and
- Informal sessions during or after onsite visits.

7805. CRITERIA FOR REVIEWING STATE PLAN AMENDMENTS FOR SPECIFIED AND ALTERNATIVE ENFORCEMENT REMEDIES

A. Introduction.--This section implements §§1919(h)(2)(A) and 1919(h)(2)(B)(ii) of the Act, as well as 42 CFR 488.303 and 488.406, and it provides guidance to the Division of Medicaid in conjunction with the Division of Health Standards and Quality in the ROs relative to reviewing for approval or disapproval, State plan amendments for enforcement remedies as specified at 42 CFR 488.406(c).

B. Specified Remedies.--Specified remedies are those remedies defined in §1919(h) of the Act as well as 42 CFR 488.406(b). The State plan must specify the State law or regulations which establish these remedies, pursuant to §1919(h)(2)(A) of the Act.

C. Alternative Remedies.--If a State wishes to establish a remedy in place of a remedy specified in 42 CFR 488.406(a) or (b), the State plan should describe the following:

1. General requirements.--These requirements include:

- o Timing and notice requirements specified in 42 CFR 488.402(f);
- o How the alternative remedy satisfies the statutory intent of the specified remedy, i.e., immediate jeopardy, non-immediate jeopardy, prolonged noncompliance, and repeat noncompliance situations;
- o When the remedy will be applied;
- o How the alternative remedy is as effective as the specified remedy in deterring noncompliance;
- o Factors considered in selecting the remedy; and
- o State law or regulations which establish these alternative remedies, pursuant to '1919(h)(2)(B)(ii) of the Act.

The States' categorization of deficiencies should result in the same scope and harm assignment.

2. CMPs.--In addition to the general requirements above, the State plan should include the following:

- o How the fine system distinguishes between fine ranges, i.e., immediate jeopardy and non-immediate jeopardy;
- o That the fine will be increased if the noncompliance is repeated on the next survey;
- o How the fine system ensures compliance; and
- o How the system deals with past noncompliance.

3. Denial of Payment for New Admissions.--Whenever an SMA's remedy is unique to its State plan and has been approved by HCFA, then that remedy may also be imposed by the RO against the Medicare provider agreement of a dually-participating facility in that State. Therefore, a ban on admissions is an acceptable State alternative, but it must be understood that in dually-participating facilities, HCFA can impose a State's ban on admissions remedy only with regard to all Medicare/Medicaid residents. Only the State can ban admissions of private pay residents.

4. Temporary Management.--In addition to the general requirements above, the State plan should describe how the alternative remedy can be imposed quickly in immediate jeopardy situations.

D. Additional Remedies.--If a State wishes to impose additional remedies to those specified in regulations, the State must describe:

- o Whether the additional remedy is in category 1, 2, or 3 (see '7400 for description of remedy categories); and
- o State law or regulations which established these additional remedies.

7807. STATE/FEDERAL DISAGREEMENTS OVER TIMING AND CHOICE OF REMEDIES

A. Introduction.--These procedures are established pursuant to "1919(h)(6) and (7) of the Act and 42 CFR 488.452 to provide guidance when the RO's findings do not agree with the SA's findings.

While HCFA expects that in most cases the RO will agree with the SA's findings of compliance or noncompliance and the timing of the SA's enforcement action, the statute provides specific rules to apply if such disagreements occur. These rules apply to non-State operated NFs and dually-participating facilities. In the case of State-operated facilities, the RO's decision always prevails because the SA does not make the certification of compliance or noncompliance nor does it make any recommendations of enforcement actions. In the case of SNFs, the RO's decision always prevails.

B. Disagreement Over Whether Facility Has Met Requirements.--If the SA finds that a facility is not in substantial compliance, but the RO finds, either through an onsite survey or review of the SA's survey findings, the facility is in substantial compliance, the SA's finding prevails.

If the SA finds a facility is in substantial compliance, but the RO finds, either through an on-site survey or review of the SA's survey findings, the facility is not in substantial compliance, the RO's finding prevails.

When the RO's finding of noncompliance prevails, the RO may:

- Impose remedies as specified in '7400;
- Terminate the provider agreement; and/or
- Stop FFP to the State for a NF at the end of 6 months.

C. Disagreement Over Decision to Terminate.--When both the SA and the RO agree that a facility is not in substantial compliance, but disagree as to whether to terminate a facility's provider agreement, the following rules apply:

- If the RO wants to terminate, but the SA does not, the RO and SMA impose the alternative remedies (pending the RO's termination at 6 months) and follow the procedures in '7600;
- If the SMA wants to terminate, but the RO does not, the SMA's decision to terminate a NF prevails as long as the termination date is no later than 6 months after the last day of the standard health survey; and
- If the facility is a dually-participating facility, the decision made for the Medicaid portion is applied to the Medicare portion and the RO imposes the decision for both programs. Any applicable appeals of alternative remedies or termination would be heard under 42 CFR 498.

D. Disagreement Over Timing of Facility Termination.--The SMA's timing of termination prevails as long as it does not occur later than 6 months after the last day of the standard health survey and both the SA and the RO agree that the facility has not achieved substantial compliance and agree that the facility should be terminated.

E. Disagreement Over Remedies.--The law provides that additional or alternative remedies may be imposed by either the State or the RO. For example, if the State decides to terminate a provider agreement and the RO

chooses to impose a CMP on top of the termination, both the termination and the CMP would be imposed. If the State chooses termination and another remedy, the additional remedy would be imposed. However, if the State and the RO both want to impose an additional remedy, only the RO's remedy would be applied.

F. One Enforcement Decision.--Only one entity certifies noncompliance and implements enforcement remedies. The State's decision prevails for a NF which is not subject to a validation survey, and the facility is entitled to an appeal under the State procedures. (See 42 CFR 431.) In the case of a dually-participating facility, if the State's decision prevails, the RO adopts the decision made for the Medicaid portion of the facility and applies it to the Medicare portion. The facility is entitled to a hearing under the Federal procedures. (See 42 CFR 498.)

7809. NATCEP AND CEP DISAPPROVALS

A. Introduction.--Sections 1819(f)(2)(B)(iii) and 1919(f)(2)(B)(iii) of the Act, as well as 42 CFR 483.151(b)(2) and 483.151(e), require denial or withdrawal of approval of facility-based NATCEPs and CEPs offered by or in a facility which, within the previous 2 years:

- Has operated under a '1819(b)(4)(C)(ii)(II) or 1919(b)(4)(C)(ii) waiver (see '4132.1);
- Has been subject to an extended or partial extended survey under "1819(g)(2)(B)(i) or 1919(g)(2)(B)(i); or,
- Has been assessed a CMP described in the Act at "1819(h)(2)(B)(ii) or 1919(h)(2)(A)(ii) of not less than $5,000, or has been subject to a denial of payment, the appointment of a temporary manager, termination, or, in the case of an emergency, been closed and/or had its residents transferred to other facilities. (See '7536 for additional information regarding CMPs.).

Also, the training will not be approved if it is offered by or in a facility unless the State makes the determination, upon an individual's completion of the program in the facility, that the individual is competent to provide nursing and nursing related services in SNFs or NFs.

Any reversals of NATCEP/CEP denial or withdrawal are limited to the informal dispute resolution process.

B. Notice.--The SA must notify the State agency responsible for NATCEP/CEP when it determines that denial or withdrawal of NATCEP/CEP approval is necessary. That agency, in turn, notifies the facility. If the noncompliance which caused a sanction to be imposed, or which caused an extended or partial extended survey to be performed, is successfully refuted by the facility or otherwise determined by the State to have been improperly cited, the facility's appeal to restore NATCEP/CEP approval will be granted.

C. Change of Ownership.--If a facility undergoes a change of ownership after having had approval of its NATCEP/CEP withdrawn for 2 years before the 2-year period has expired, the remainder of the 2-year period does not carry over to the new owner. If the facility meets all the other requirements for NATCEP/CEP, its program(s) will be approved.

Disclosure

7900. INFORMATION DISCLOSED TO PUBLIC

As provided in "1819(g)(5) and 1919(g)(5) of the Act and 42 CFR 488.325, the following information must be made available to the public, upon the public's request, by the SA, SMA, or HCFA for all surveys and certifications of SNFs and NFs:

- The fact that a facility does or does not participate in the Medicare/Medicaid program;

- The official Statement of Deficiencies, Form HCFA-2567. If it contains the name of any individual, medical information about any identifiable resident, the identity of a complainant, or the address of anyone other than an owner of the facility, that information must be blocked out before the Form HCFA-2567 is released to the public;

- Acceptable PoCs, Form HCFA-2567. If the PoC contains the name of any individual, medical information about any identifiable resident, the identity of a complainant, or the address of anyone other than an owner of the facility, that information must be blocked out before the Form HCFA-2567 is released to the public;

NOTE: The Statement of Deficiencies and PoC are contained side by side on one form, Form HCFA-2567. The Statement of Deficiencies can be released before the PoC portion has been completed by the provider. After an acceptable PoC is submitted, however, the two portions are released simultaneously since they appear on the same form.

- A list of isolated deficiencies that constitute no actual harm and have the potential for minimal harm will be included with the Form HCFA-2567 when applicable;

- Provider comments;

- Statements that the facility did not submit an acceptable PoC or failed to comply with the conditions of imposed remedies, if appropriate;

- Official notices of provider terminations;

- Statistical data on provider characteristics which does not identify any specific individual. 42 CFR 401.120 states that records will not be created by compiling selected items from the files to give the requester data such as ratios or percentages. However, if existing documents contain such statistical data (i.e., OSCAR reports), they are subject to release;

- Final appeal results;

- Medicare and Medicaid cost reports;

- Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in 42 CFR 420.201; and

- Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in 42 CFR 420.201, who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law.

7901. REQUESTING PUBLIC INFORMATION

The public may request information in accordance with disclosure procedures specified in 45 CFR Part 5.

7902. CHARGES FOR INFORMATION

If a member of the public requests copies of the records and information described in '7900 from HCFA, there will generally be a charge. Charges should be in accordance with 42 CFR 401.140 for Medicare and applicable State procedures for Medicaid.

7903. TIME PERIODS FOR DISCLOSING SNF/NF INFORMATION

A. Information That Must Be Disclosed Within 14 Days of Request.--Upon the public's request, the SA, RO, or SMA, where appropriate, must make the following information available to the public within 14 calendar days after each item is made available to the facility:

- Statements of Deficiencies (Form HCFA-2567);
- Separate listings of any isolated deficiencies that constitute no actual harm, with the potential for minimal harm; and
- Approved PoCs (Form HCFA-2567) (which contain any provider response to the statement of deficiencies).

B. Disclosure Timeframes.--Although the SA or RO may choose to wait as many as 14 calendar days before disclosing the information listed in subsection A in order to obtain a provider response or PoC prior to disclosure, the information may be disclosed at any time after it has been made available to the facility. The information could be disclosed as quickly as the day after it is made available to the facility, or as many as 14 days afterward. The determination of the appropriateness of the timing of the disclosure is made by the SA or RO.

In situations generating media interest, the SA should notify the RO prior to the initial public release of the Form HCFA-2567. ROs are expected to extend the same courtesy to SAs when RO survey findings have the potential for high publicity.

7904. INFORMATION FURNISHED TO STATE'S LONG TERM CARE OMBUDSMAN

A. Information Given to Long Term Care Ombudsman.--The SA must provide the State's long term care ombudsman with the following:

- A Statement of Deficiencies reflecting facility noncompliance and, if applicable, a separate list of isolated deficiencies that constitute no actual harm with the potential for minimal harm;
- Reports of adverse actions specified in 42 CFR 488.406 imposed on a facility;
- Any written response by the provider, including PoCs and provider requests for informal dispute resolution; and
- A provider's request for an appeal and the results of any appeal.

B. Federal Surveys.--For Federal surveys, HCFA will contact the SA and provide the information needed for the State to notify the ombudsman on HCFA's behalf.

7905. INFORMATION FURNISHED TO STATE BY FACILITY WITH SUBSTANDARD QUALITY OF CARE

A. Information Provided to the SA by Facility.--To provide for the notice to physicians required under "1819(g)(5)(C) and 1919(g)(5)(C) of the Act, not later than 10 working days after receiving a notice of substandard quality of care (as defined in 42 CFR 488.301), a SNF or NF must provide the SA with a list of:

- Each resident in the facility with respect to whom such finding was made; and
- The name and address of his/her attending physician.

B. Failure to Provide Information Timely.--Failure to disclose the information within 10 days as required in subsection A will result in termination of participation or imposition of alternative remedies.

C. Federal Surveys.--In the case of a finding of substandard quality of care based on a Federal survey, the RO will instruct the facility to provide the necessary information to the SA.

7906. INFORMATION FURNISHED TO ATTENDING PHYSICIAN AND STATE BOARD

A. State Notification of Noncompliance.--Not later than 20 calendar days after a SNF or NF complies with '7905.A, the SA must provide written notice of the noncompliance to:

- The attending physician of each resident in the facility with respect to whom a finding of substandard quality of care was made; and
- The State board responsible for licensing the facility's administrator.

B. Federal Surveys.--If the finding of substandard quality of care is based on a Federal survey, the SA will provide notification of noncompliance to the above parties after receiving the necessary information from the SNF or NF. (See '7905.C.)

7907. ACCESS TO INFORMATION BY STATE MEDICAID FRAUD CONTROL UNIT (MFCU)

In accordance with the procedures in 42 CFR 455.21, the SA must provide access to any survey and certification information incidental to a SNF's or NF's participation in Medicare or Medicaid to a State MFCU as defined at 42 CFR Part 1007, consistent with current State law and the operating agreement between the SA and the MFCU.